Spinal surgery is a costly specialty that strains OR budgets. The wide variation in techniques and costly technology make it difficult to manage. Challenges go beyond rods and screws. An array of biologics, such as bone morphogenic protein (BMP) and demineralized bone matrix (DBM) can add thousands of dollars to a case.

With costs averaging about $3,000 a case, BMP alone has a dramatic impact on the budget. Yet definitive evidence is lacking on its indications and cost-effectiveness. Medtronic, which sells the leading BMP product, Infuse, has faced scrutiny lately over widespread off-label use. The company disclosed in November it has received a subpoena from the US Department of Justice over off-label use.

Other bone grafts and substitutes such as the putties, pastes, and crunches are becoming just as expensive.

“The costs of the newer products are significantly higher than their predecessors and will present the next challenge to hospitals trying to manage their implant costs,” writes Stan Mendenhall, publisher of Orthopedic Network News (ONN, www.orthopedicnetworknews.com) in his annual spine update in October 2008. Two products, Osteocel and Pro-Dense, list for over $5,000.

Beyond the technology are other business issues.

“You also need to focus on your contracting, coding, reimbursement, and overall costs,” adds Julie Blatnik, RN, BSN, CNOR, director of the spine program for HealthEast Care System, St Paul, Minnesota.

There are no easy answers to managing spinal surgery costs. This article offers some areas for OR leaders to consider.

A host of supplements

Spinal surgery is aided by a host of supplements intended to help vertebrae to knit. They range from BMP, which actually induces bone growth, to other products that act as scaffolding for new cells, such as donor bone, DBM, and ceramic-based products.

HealthEast, which expects to do about 2,000 spine cases during this fiscal year, estimated it would spend about $1.8 million on BMP alone.

In managing spinal surgery, ORs tend to focus on the hardware. But they may not have a handle on the biologics, notes Zee Robertson, MBA, senior director of client services for VHA Inc, who consults with hospitals on cost management and product utilization.

“A hospital will say, ‘We’re making money on our spine cases.’ But have they really taken into account the cost of everything they are using?” says Robertson. “They may think the cost is in the metal components, but you have to look at all supplies—the biologics and interbody fusion devices as well as the hardware.”

Eliminating BMP products is not realistic because these are the only known proteins shown to induce formation of new bone. In 39 spine programs monitored by ONN, BMP was used in 62% of lumbar fusions during 2008, up from 52% in 2007, though the difference may reflect a change in the hospital sample.

Overall, implant costs per procedure declined modestly in 2008 to $15,351 for a lumbar fusion and $5,975 for a cervical fusion, according to ONN. Implant costs per case for a lumbar fusion were up by 120% in 2008 over 2001.
**BMP versus DBM**

The 2 BMP products on the market that have been demonstrated to grow bone are BMP-2 (Medtronic’s Infuse) and BMP-7 (OP-1 from Stryker). Infuse has a far larger market share, accounting for over 94% of BMP usage in 2007, ONN reports. Infuse was approved by the Food and Drug Administration (FDA) for a narrow application in spinal surgery: use with the LT-Cage implant for single-level treatment of degenerative disc disease. But that application has faded, and the vast majority of Infuse is now used off-label. OP-1 is available under a humanitarian device exemption for use in revision posterolateral lumbar spinal fusion and treatment of long-bone fracture nonunions.

Other companies may claim their products do the same thing as BMP, but talk with your surgeons before making a change, cautions Robertson.

There are products with both BMP and DBM but in varying proportions. BMP and DBM have different properties. DBM provides a scaffold for cells in building bone, while BMP provides the protein that instructs cells to become bone. Look carefully at the package, Blatnik advises. Some DBM products are only 2% to 3% BMP, while others are 30% to 50%.

“The package will list a carrier, a scaffold, and the BMP. You have to look at the percentage of BMP,” she says. Even physicians who use the products may not know the differences.

The best approach to sorting out the confusing array of products, she suggests, is to enlist a physician advisor who understands orthobiologics. Ideally, the physician will be independent of the spine surgeons at your facility and will provide an objective voice.

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**Practice variation example**

Posterior thoracic/lumbar 2 level: Average total implant cost per patient

<table>
<thead>
<tr>
<th>Physiciss</th>
<th>Hardware</th>
<th>Interbody fusion devices</th>
<th>Bone products</th>
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*Source: Goodroe Healthcare Solutions, a VHA Company. Used with permission.*
An evidence gap

With so much off-label use of BMP-2, information is lacking to guide organizations in decision making.

“There is a huge evidence gap,” says Susan Levine, PhD, vice president of health care technology research and consulting for Hayes, Inc, a consulting firm that provides independent analysis on health care technologies (www.hayesinc.com).

“One problem is that off-label use is happening without formal FDA approval or clinical studies. The manufacturer doesn’t have much of an incentive to fund a study.” She adds: “I think we need to encourage people, though it may not be practical to do a formal clinical trial, at least to enroll patients in a registry or conduct a case-series study so patients are followed and monitored. Then if there are problems, they can be reported and information shared.”

She recommended working with physicians on patient selection criteria. “Be sure there is a rationale for using BMP, other than a patient having a spinal fusion. Look at characteristics that might indicate the patient is at risk for a delayed fusion or that there are contraindications to using an autologous graft.” Examples are smoking, osteoporosis, and a previous iliac crest harvest. The hospital should also expect physicians to disclose any financial benefit they gain from use of the product.

BMP and patient safety

The FDA warned in July 2008 about complications from using BMP in the cervical spine. The FDA said it had received at least 38 reports of complications in the past 4 years from use of BMP in the cervical spine. These included swelling of the neck and throat, which compressed the airway or caused strictures in the neck, with reports of difficulty swallowing, breathing, or speaking. Severe dysphagia has also been reported.

The FDA said the cervical spine’s proximity to the airway contributed to the seriousness of the events. Emergency care was often necessary.

Safety and effectiveness of BMP for treating cervical spinal conditions have not been demonstrated, the FDA said. The agency recommended that physicians use approved alternatives or consider enrolling in clinical studies. The FDA reminded facilities to report deaths and serious injuries associated with use of medical devices, even if off-label use is involved.

Report events to the FDA’s MedWatch program by phone at 800/332-1088 or online at www.fda.gov/medwatch/report.htm.

BMP outcomes and indications

Some perspective on BMP outcomes and indications comes from an independent technology assessment produced in 2007 for Britain’s National Health Service. The report evaluated 12 randomized clinical trials on use of BMP in spinal fusion. Of these, 7 trials were sponsored by industry and 5 by other groups. The authors found the trials had flaws, and none met all of their quality criteria.

For lumbar fusion, the assessment found overall, use of BMP-2 seemed more effective than the patient’s own bone for a single-level fusion for degenerative disc disease. Use of BMP reduced OR time by an average of 25 minutes and led to a somewhat shorter hospital stay. Some evidence suggested patients receiving BMP had greater improvement in disability scores and less back and leg pain. Data on patients returning to work was limited and hard to interpret. The authors could not determine convincingly the effect of BMP on adverse events or secondary treatments such as repeat surgery.

They found little evidence on BMP use in cervical fusion, spondylolisthesis, or spinal stenosis.

After a detailed economic analysis, they concluded that overall, use of BMP for spinal fusion in the UK “is unlikely to be cost-effective.”

Ethics and use of biologics

Infuse, with its widespread off-label use, has been caught up in the controversy about the financial relationships between physicians and industry. The Department of Justice subpoena is a reflection of that.
The scrutiny is thought to be one reason Medtronic’s biologics sales were flat in its second quarter, the company’s CEO, Bill Hawkins, told investors in a November conference call. Another is the FDA warning last summer about complications from use of BMP in the cervical spine.

With most of Infuse used off-label, whistleblower lawsuits have alleged Medtronic gave physicians attractive perks, like sham consulting arrangements and lavish trips, to promote the off-label use.

Articles in the Wall Street Journal and The New York Times reported on company payments to physicians and the whistleblower suits by former Medtronic employees. Congress is probing the arrangements. Medtronic says the allegations were made years ago, and it has strict guidelines regarding promotion of its products. The company said it is cooperating with the Department of Justice.

Given the legal climate, physicians are reluctant to comment on indications for use. When OR Manager asked a prominent spine surgeon who is an expert on BMP for his perspective, he declined, citing the lawsuits.

**What’s the ethical approach?**

The cost, commercialism, and ethics of orthobiologics were discussed in a 2007 symposium in the Journal of Bone and Joint Surgery. The authors, who included physicians, an ethicist, and a Medtronic scientist, pointed out that the cost of Infuse is about the same as harvesting the patient’s own bone, at about $2,250 to $4,154, but BMP has the advantage of sparing the patient the pain and risk of the bone harvest.

The authors say they believe innovative use of such products for individual patients need not be considered research. But ethical norms should apply. Two ways to help ensure ethical use are peer review and disclosure to patients. The authors say surgeons should disclose to patients if they receive a royalty for using a device. They should also tell patients if a device is being used off-label and should explain why they believe it is the best choice for the patient.

> —Pat Patterson

**References**


Getting a handle on spine surgery

Strategies for managing this costly specialty.

Find out what you’re using

Hospitals often don’t have a handle on all of the products they are using in spine surgery.

“Hospitals tend to concentrate on the metal components, but they don’t mind the store when it comes to bone and bone substitutes,” says Zee Robertson, MBA, of VHA Inc.

Hospitals often use a number of vendors, especially for DBM, without a clear understanding of the products and what they do. To start with, she suggests developing product categories for tracking these products using an unoccupied field in the materials management information system. Categories might include:

- allograft bone
- bone morphogenic protein (BMP)
- bone substitutes (eg, Vitoss, CopiOs, TrueForm CP, MasterGraft)
- demineralized bone matrix
- interbody fusion devices, nonbone
- machined bone
- platelet concentrators.

Hospitals also need a strategy for monitoring off-label use of BMP. Robertson suggests having the medical director or another physician leader work with the surgeons to make sure usage is efficacious.

Exercise portion control

Of some help to OR budgets, BMP-2 (Infuse) now comes in smaller packages, with the extra-extra small (0.7 cc) listed at $850 and small (1.4 cc) at $1,675. Large and large II packages are listed at $5,250. “Be sure to look at the smaller packages, especially if you have surgeons using BMP in the cervical area or outside the spine in areas like hand and foot surgery,” says Julie Blatnik, RN, BSN, CNOR, director of the spine program for HealthEast Care System, St Paul.

Also consult with your staff. “Ask them if they are using large or extra large packages for certain types of cases and if they are throwing any away,” she says.

Robertson suggests setting up a spreadsheet or grid to track volume (package sizes), number of levels fused, and wastage by procedure. If a pattern is detected, you may be able to buy smaller packages for some cases.

Code accurately

Important coding changes for spine were introduced in 2008 with the MS-DRGs. Make sure coders are up to speed and informed when a new technology is added, Blatnik urges. Some highlights:

- With MS-DRGs, an anterior/posterior spinal fusion, formerly in DRG 496, now has 3 codes, DRGs 453, 454, and 455, each with 3 levels to indicate complications:
  —without comorbidities and complications (CCs)
  —with CCs
  —with multiple comorbidities and complications (MCCs).

For spinal fusion cases with MCCs, reimbursement went up significantly, but examine your volumes and caseload to see how many procedures will actually fall in the new MCC category. There were also changes in what qualifies as a CC for coding purposes. Insulin-controlled diabetes, for example, no longer qualifies as a CC, meaning there is no additional reimbursement.

“For a typical fusion, for the majority of hospitals and cases, you are receiving less money because you don’t have those complications,” she says. Physicians need to be informed about this, she adds, because they may not receive accurate information from vendors.

- Be sure coders know correct codes for new technology. Though these codes may
not make a difference in the DRG payment, coding for new technology is important because that is how Medicare captures data to use in future payment rate adjustments.

- Also watch outpatient coding carefully. Medicare now reimburses for certain spine cases in the outpatient setting, including posterior and posterolateral fusions—but the codes for instrumentation and grafts are still classified as inpatient only. That means these procedures are payable in the outpatient setting only if they use no spine instrumentation or interbody devices.