

Materials management

Will a 'perfect storm' help control rising orthopedic implant costs?

It may well take the perfect storm of federal investigations, legislation, unprecedented hospital and surgeon cooperation, and voluntary changes in manufacturers' business practices to control rising hip and knee implant costs, say experts interviewed by *OR Manager*.

But many believe once the storm is over, hospitals will begin to see relief from ever-rising implant costs. Once money-makers for surgery departments, hip and knee implant procedures at many hospitals now have margins that are slim, nonexistent, or bright red, experts say.

From 2003 to 2004, implant prices climbed 9%, while Medicare reimbursement rose only 2.4%, according to *Orthopedic Network News*, which tracks implant costs (related article, p 13).

Some developments during the first half of 2005 that may help hospitals on implant prices:

- In February, the Office of the Inspector General (OIG) of the Department of Health and Human Services issued 6 advisory opinions that seemed to give the green light to certain types of gainsharing arrangements—programs that financially reward physicians for participating in hospital supply cost-containment projects. (See www.oig.hhs.gov/fraud/advisoryopinions/opinions.html. Read opinions 05-01 to 05-06.)
- In March, the US Department of Justice (DOJ) issued subpoenas to large orthopedic implant manufacturers, seeking information about their financial relationships with orthopedic surgeons.
- In April, AdvaMed (the Advanced Medical Technology Association), a trade association for medical device manufacturers, issued updated ethical guidelines on the interaction between vendor representatives and health care professionals. The additions primarily cover gifts and appropriate payment for services. (See www.advamed.org/publicdocs/coe_with_faqs_4-15-05.pdf.)
- In May, Senators Charles Grassley (R-Iowa) and Max Baucus (D-Mont) introduced specialty hospital legislation that included a provision to allow gainsharing, or "coordinated-care incentive arrangements," between hospitals and doctors. The Medicare Payment Advisory Commission (MedPAC) in February also endorsed the concept of gainsharing.

"The resurgence of gainsharing and the device manufacturers' subpoenas will have the dual effect of helping hospitals lower prices," says Gadi Weinreich, chairman of the national health care group in the Washington office of Sonnenschein Nath & Rosenthal.

"The tables are starting to turn toward hospitals," he says. "It is not the beginning of the end; rather, it is the starting point of a long process. Solutions need to be found, but these subpoenas will lead to a number of changes in the number and content of financial arrangements among device manufacturers and physicians. This, in combination with the continued evolution of gainsharing, may jump-start the movement toward lower prices."

"The latest and greatest"

From 1991 to 2004, orthopedic im-plant prices jumped 132% while hospital reimbursements rose only 16%, according to *Orthopedic Network News*.

In 2004, knee implants cost a typical orthopedic program \$4,200, an increase of 42% from about \$3,000 in 2000, says Dan Piro, senior vice president of Aspen Healthcare Metrics, an Englewood, Colo.-based consulting firm. In 2004, hip implants cost about \$5,600, up 60% from about \$3,500 in 2000, according to Aspen data.

“The data shows there were very few programs with positive margins. For primary hips and knees, it is difficult to make money, and it is getting worse,” Piro says.

The biggest reason why hips and knees do not make money is the difference between reimbursement and costs, he says. “To a lesser extent, there is the competitive problem of business lost to ambulatory surgery centers,” he says.

Bill Anton, BA, RRT, business director of surgical services at the University of Washington Medical Center, Seattle, says patients and surgeons drive some of the implant cost increases.

“The American public wants the latest and greatest, no matter what it costs,” Anton says. “Surgeons also want the best for their patients, and that costs the most.”

According to Anton, these are some reasons costs have escalated and margins have declined:

- Vendor relationships with surgeons that tend to drive up the cost of implants.
- A disconnect between surgical procedures that pay surgeons high professional fees and hospitals’ low facility fees. The result is the hospital loses money on certain procedures.
- Lack of incentives for surgeons to reduce hip and knee implant costs.
- Rapid introduction of new implants and other products into the market.
- Lack of a rigorous value analysis process for new products coming into the hospital.

Adds Piro: “Price increases are fueled because (orthopedic implant) companies are publicly traded, and there is pressure from Wall Street to meet and exceed expectations.”

But there are steps hospitals can take to reduce implant costs. “The most important thing you can do first is have a meaningful dialogue with your surgeons,” Piro says.

What can hospitals do?

Three main strategies hospitals have used to control costs are:

- collecting cost and quality data and sharing it with physicians to encourage efficient use of resources
- standardizing implant products with a few vendors to get better pricing and management control
- capitulating implant prices to fixed procedural costs.

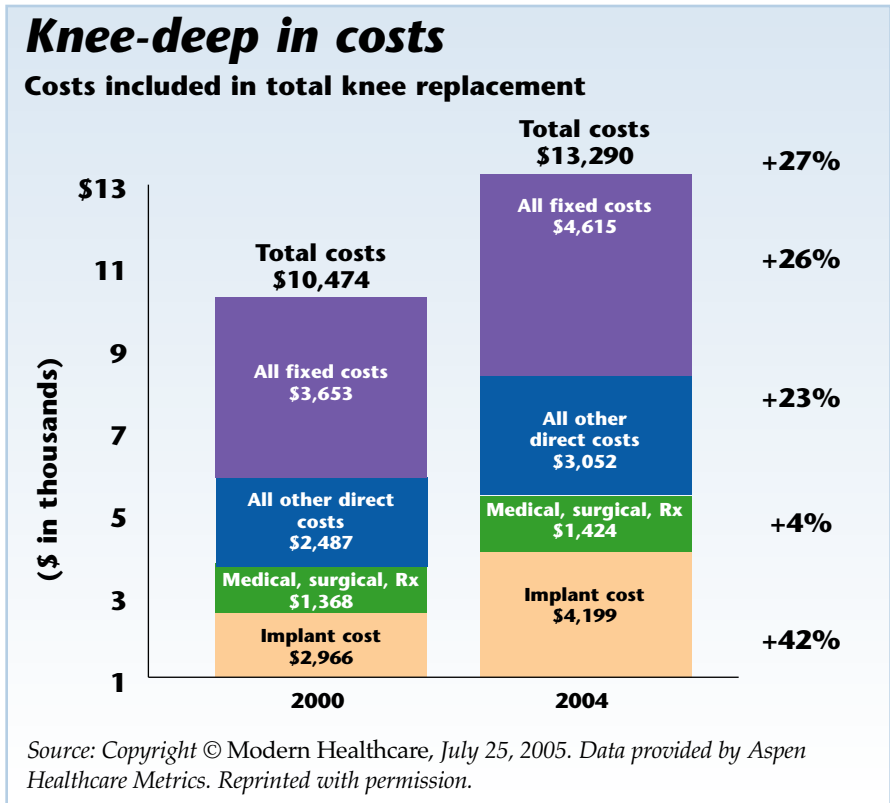
“Some hospitals don’t share data with physicians because they don’t trust their data,” Piro says. “You need to (find ways to) collect the data, open the kimono, and share it with your surgeons.”

Anton says, “Once the doctors understand how much procedures cost and what the reimbursement is, many times they will cooperate for the overall benefit of the hospital.”

In exchange, hospitals should be prepared to make efficiency and quality improvements in the OR. “Surgeons are making a lot less money on (Medicare) cases, and if a hospital can make life easier in the OR, you will get cooperation from doctors,” Piro comments.

The next step is standardizing implants. “It makes it easier to negotiate with vendors because they base their discounts on market share and spending,” Anton says. “Doctors will object, and sometimes hospitals will stop short because of political considerations.”

Surgeons generally don’t want to standardize because they have developed brand loyalty and built strong relationships with vendor representatives, Piro says.



Capping implant prices

One way to avoid wide-scale standardization is to negotiate capitated implant contracts with vendors, Piro says.

“Capitating implants, or setting price matrixes, preserves surgeon choices,” Piro says. “Many doctors look at specific knee and hip implant constructs as homogeneous products. When they see that what the hospital pays for similar products is all over the board, they often believe it is fair (to capitate).”

Vendor companies don’t like capitation, he notes. “It doesn’t increase their market share; it just lowers their price,” Piro says.

Still, capping implant costs can be a winning strategy, Piro says. But it requires complete buy-in from surgeons and the administration. “It is a difficult strategy unless you have complete support,” he says.

Once the decision is made to offer capitated contracts, Piro says the danger exists that vendors will refuse. “Doctors and the administration have to stick to their guns and be prepared to lose a product,” he says. If one or more vendors drop out, the hospital in effect moves to standardization through a capitation strategy, he adds.

Finally, the hospital needs a system for constant monitoring of the capitated contracts because vendors are astute at adding new products that fall outside of the contract.

“You need to be aware of upcharges, carveouts, and exceptions,” he says. “These companies have vast experience, and if you are not diligent, they can outfox you.”

Putting in place a technical review committee to assess new products is essential “so you don’t slip and roll down the hill,” Piro says. New products—if they are sufficiently different from current ones and provide value—can be negotiated outside the capitated contract, he says.

“Real savings are possible (with capitation),” Piro says. “The issue is to make it sustainable. You have to put in safeguards, continue with physician relationships; listen to their needs, and you can succeed.”

Beef up product evaluation

Though most hospitals use a product entry evaluation process, Anton says he is surprised by how many either don’t assess new products or do a poor job.

“Hospitals need some way to control and slow down the entry of products so you have the time to look at pricing and make sure it is FDA (Food and Drug Administration) approved so you can bill Medicare for it,” says Anton, adding: “Some hospitals don’t have anything in place, probably for political reasons, and these are big-time institutions.”

Effective product entry processes require a hospital administration willing “to take the heat from physicians,” Anton says.

Each week, Anton receives 1 to 2 new product requests from surgeons. The approval process can take from 3 to 4 days for emergency cases to as long as 6 to 12 weeks, depending on whether the FDA has approved the device and how long price negotiations with vendors take.

Meanwhile, “the surgeon is stewing,” Anton says. “The worst case is the surgeon will schedule a case (before the implant is approved for use at the hospital). This puts us in a bad position. We have to go fast to set up billing, and we may not get the best prices.”

Still, using the hospital’s implant product evaluation committee, Anton says the system saved \$243,000 in surgical implants over the last 12-month period. “If we didn’t have that process, it could add \$300,000 to \$400,000 in additional costs,” he says.

Where is gainsharing going?

The financial disconnect between surgeons and hospitals is one of the drivers of implant costs. Gainsharing is designed to connect incentives. While details are complex, the concept is quite simple: Cost savings on supply costs are shared between physicians and the hospital.

In 1999, gainsharing programs fell off the map when the OIG stated in an opin-

ion that they probably violated the Civil Monetary Penalty (CMP) statute that prohibits direct or indirect payments to physicians for reducing or limiting items or services to Medicaid or Medicare patients.

But based on the OIG's new encouraging gainsharing opinions, HCA, the Nashville, Tenn.-based for-profit hospital chain, began in June to implement a gain-sharing project for hip and knee implants at its 160 hospitals, says spokesman Jeff Prescott. Although the OIG hasn't issued an opinion on the project yet, Prescott says HCA is signing up physicians and offering them financial incentives.

"We will hold (the savings) in escrow until we get (OIG) approval," he says. "If the surgeons use the implants, the savings are allocated back out, aggregated by division, and based on procedures they will do."

Prescott says HCA has struck 3-year deals with Zimmer, DePuy, and Stryker. HCA expects to save 10% to 20% on covered implant supplies

A missing piece

Most experts believe gainsharing will eventually become commonplace.

"This year we had a revival in the concept of gainsharing," Weinreich says. "Each OIG opinion was slightly different because the protocols were different. But the common feature is that hospitals would work with physicians to standardize certain high-cost medical supply and device items, and manufacturers would give hospitals a better price based on increased sales volume."

While the OIG said these arrangements still would probably violate the CMP statute, the OIG also said it would not impose sanctions because of clinical and product safeguards incorporated in the specific programs, Weinreich says. "This opinion is limited to the requesters of the opinion," he adds.

The opinions cite reasons why the OIG would not pursue violations of the CMP law. Among them were establishing baseline thresholds beyond which no savings would be shared with physicians and distributing incentives on a per-capita rather than on an individual basis.

One missing piece of the equation, however, is how gainsharing affects the Stark anti-kickback law that prohibits physician self-referrals, Weinreich says.

"The OIG correctly observed that it is not authorized to comment on Stark," he says. "That analysis is important because Stark is a strict liability law. It is unclear whether gainsharing models violate Stark."

The Centers for Medicare and Medicaid Services is the principal regulatory agency on Stark, and Weinreich says CMS has not voiced an opinion on gainsharing yet.

"CMS has a historic interest in gainsharing," he says. "CMS sought to work with hospitals in a pilot project in New Jersey, but that was halted due to some competing hospitals that got a judge to enjoin the program."

One way to resolve the issue, he says, is for federal legislation to be approved. "The bill proposes safe harbors for gainsharing that would be permitted under Stark," he says.

Weinreich says he is aware many hospitals are working on gainsharing programs. "You must tell your client gainsharing could well violate the law unless you have a specific opinion from the OIG," he says. "There is no question that the advisory opinions have started something that can't be put back in the box."

Weinreich says the OIG's opinions show there is recognition within government that gainsharing can be a good thing. "We need to get there somehow, and a legislative fix is coming eventually," he says.

What is DOJ looking for?

Another development that may give hospitals leverage to reduce implant costs is the subpoenas issued to large implant manufacturers.

Weinreich says the DOJ is looking for improper payments to orthopedic surgeons from vendors. Some services like research or testing are legitimate, he says, and if paid at fair market may not raise any problems. However, the DOJ may find kickbacks are part of these agreements, he says.

Nothing is directly known about the subpoenas because defense lawyers for the companies aren't talking, Weinreich says. It could take 2 to 3 years before details of the subpoenas are revealed, and some action is taken by the DOJ, he says.

"My understanding is that the subpoenas are very broad," Weinreich says. "They seek all contracts and financial arrangements with any orthopedic group or individuals who are orthopedic surgeons. The DOJ wants to look at consulting agreements, speaking engagements, and personal services between manufacturers and surgeons who use those devices."

He says it is possible that the investigation may identify a number of arrangements the government may deem worth additional scrutiny and enforcement action. The short-term effects of the subpoenas, says Weinreich, could lead individual companies to tighten ethical standards.

"We are likely to see that even companies with good compliance might bolster their efforts, and companies with looser controls about the agreements they enter might use this series of events to tighten their controls," he says. "Those who are unscrupulous will probably try to continue."

The impact on surgeons will most likely initially chill relationships with vendors, he says. "Physicians will change some conduct and ask more questions about relationships and financial dealings," he says.

As a result, the subpoenas will create an incentive for physicians to work with hospitals like they never have before, Weinreich says. "The real opportunity to reduce prices will come in conjunction with gainsharing." ♦

— Jay Greene

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