

Hip And Knee Implants: Current Trends And Policy Considerations

Escalated demand and costs for replacement surgeries could be a detriment to the overall welfare of the U.S. population.

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ABSTRACT: This paper constitutes an analysis of the issues, relationships, emerging hospital strategies, and policy needs surrounding hip and knee implants. Demand for hip and knee replacements is rising annually, and growth is expected to be substantial. Costs are high, reaching \$11 billion for hospitals in 2004 and \$5 billion for Medicare in 2006. Relationships among stakeholders add complexity. Case studies reveal emerging strategies by hospitals for management of implants. Policy considerations include development of a national council for data and technology assessment, a national joint registry, price transparency, and incentives. [*Health Affairs* 27, no. 6 (2008): 1587–1598; 10.1377/hlthaff.27.6.1587]

IN THEIR MEDICAL PRACTICES, PHYSICIANS tend to select medical devices and equipment for their patients based on their familiarity with and loyalty to certain products. Such expensive devices and equipment are known as physician preference items (PPIs). Examples of PPIs include hip and knee implants, cardiac stents, and spinal implants.¹ Because of the expense of such products, hospitals, payers, and group-purchasing organizations (GPOs) have increasingly dedicated their resources to improving the products' clinical and cost-effectiveness. This paper focuses on one set of PPIs: hip and knee implants.²

Given the projected increases in hip and knee replacements in the United States, the current expense of implants, and the cost to Medicare, this is an important area to analyze, considering which policy changes can prepare us for the future.³ Medicare could be facing a bill close to \$50 billion for these procedures alone by 2030 (based on current projections and Medicare payment levels).⁴

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This paper presents an analysis and discussion of issues of demand, cost, reimbursement, stakeholders, and relationships that involve implants. Discussion is grounded in our analysis of issues and relationships related to implant choice, emerging hospital strategies for implant management, and international efforts surrounding implants. We conclude with policy recommendations.

The Issues

Hip and knee replacement surgeries are two of the most commonly performed and effective operations in the United States.⁵ As the number of replacement procedures continues to rise, there is increased focus on strategies and policies to manage costs and ensure the appropriate use of implants.⁶

■ **Growing prevalence.** The approximately 750,000 U.S. hip and knee replacements performed in 2005 represent a 70 percent increase over a five-year period.⁷ Escalating demand is expected to continue from patients seeking improved quality of active life. The obesity epidemic and need for revision surgery have additional implications.⁸ By 2030 the demand for primary and revision hip replacements is projected to more than double, while the demand for primary and revision knee replacements is projected to increase more than 600 percent. A projection for the total number of replacements by 2030 is nearly 4.5 million.⁹

The U.S. market for implants reached \$5 billion in 2005, double what it was in 2002.¹⁰ Zimmer, one of the largest manufacturers of implants, doubled its net sales of implants between 2003 and 2007.¹¹ The average selling price for total hips increased 132 percent during 1996–2006.¹²

■ **Hospital costs for implants.** Hospital costs for implant procedures are high. During 2000–2004, knee arthroplasty was one of the top ten commonly performed procedures, with the most rapidly increasing hospital inpatient costs for all payers. Hip replacement was a top-ten commonly performed procedure with the most rapidly increasing inpatient costs for private insurance.¹³ In 2004 there were 488,000 hospital stays in U.S. hospitals for knee arthroplasty procedures, with mean length-of-stay of 3.9 days and mean cost of \$13,200 per admission. In the same year there were 368,000 total and partial hip replacements, with mean length-of-stay of 5.0 days and mean cost of \$14,500. Aggregate costs were \$6.3 billion for knees and \$5.3 billion for hips.¹⁴

■ **Payers' costs.** The costs to payers for implant surgeries are also high. Medicare, the biggest payer for U.S. joint replacements, averaged payments of \$11,000 for primary surgeries and \$14,000 for revisions in 2006.¹⁵ Diagnosis-related group (DRG) 544 (major joint replacement or reattachment of lower extremity) was the highest inpatient hospital short-stay cost for Medicare in fiscal year 2006. For this DRG combined with DRG 545 (revision of hip or knee replacement), Medicare paid more than \$5 billion in 2006.¹⁶

■ **Costs versus reimbursements.** There is a growing gap between costs and reimbursements. Hospital reimbursements from Medicare for total joint replacements

between 1991 and FY 2008 rose 27 percent, while the average selling price for hip implants rose 132 percent between 1996 and 2006.¹⁷ The cost of the implanted device can account for 50 percent or more of reimbursement.¹⁸

Medicare could be facing a huge bill for hip and knee replacements by 2030. Increasing costs, declining reimbursements, and narrow profit margins for hospitals represent factors that could lead to hospitals' reassessment of the long-term financial viability of total joint replacement service lines.¹⁹ If this should occur, the potential public welfare cost would be high.

Stakeholders

Selection, purchasing, and reimbursement of Food and Drug Administration (FDA)-approved products make their way from manufacturer to patient under the influence of various stakeholders, including the hospital, supplier, physician, GPO, distributor, payer, and patient.²⁰ Understanding the challenges of relationships among these parties helps set the stage for understanding policy needs.

■ **Hospitals.** Despite the economic risks that accompany increased demand for and costs of implants, and declining profit margins for these surgeries, many hospitals continue to offer physicians an unconstrained choice of implants.²¹ This may reflect fear that physicians will leave their facility if cost containment efforts are made; absence of adequate managerial leadership, infrastructure, or resources; or a lack of adequate data for product assessments.²²

Early initiatives by hospitals to influence implant use and cost included periodic product assessment through value analysis teams (VATs), informal "gain-sharing," and implant formulary models. Support has come from GPOs and consulting firms.²³ These initiatives have shown uneven success.

Hospitals' efforts to encourage orthopedic surgeons to consider implant costs in their decision making are often rejected. Many physicians feel that efforts such as VATs and technology assessment committees (TACs) are motivated by hospitals' overarching concern with controlling costs at the expense of high-quality patient care.²⁴

Hospitals' relationships with implant vendors contain underlying conflict surrounding costs, product use without prior approval, and suppliers' view of the physician as customer. Hospitals' vendor management policies are viewed as restrictive and intrusive by both vendors and the physicians they serve, contributing further to conflict among hospitals, suppliers, and physicians.²⁵

■ **Suppliers.** In considering the physician as their customer, suppliers focus on where product choice rather than payment lies. These relationships, augmented by service, help influence physicians' product choices.²⁶

Suppliers and orthopedic surgeons may additionally forge relationships based on consulting that includes physicians' involvement in product development, training, and continuing medical education. The U.S. Department of Justice (DOJ) investigation of these relationships has resulted in civil financial settlements, com-

pliance rules, and federal monitoring of five implant manufacturers.²⁷ The effect of this heightened scrutiny and requirement for transparency is as yet unknown. Also, supplier-mandated nondisclosure agreements provide suppliers with leverage in negotiating contracts yet prevent hospitals, physicians, and patients from having open price information.²⁸

■ **Physicians.** Physicians, who have traditionally determined implant choice and surgery location, are facing greater pressure from hospitals for involvement in evaluation of cost-effectiveness and may operate in hospitals where implants are standardized. Some payers have developed programs, such as the UnitedHealth Premium physician designation program, whereby physicians are evaluated on quality and cost-efficiency criteria. High scores lead to fee-schedule enhancements.²⁹

There is heightened criticism of physician-supplier relationships and controversy over the appropriate oversight. The U.S. DOJ investigations have pushed this area into public scrutiny. Academic medical centers have pressed for stronger regulation and transparency in physicians' supplier relationships vis-à-vis industry-supported gifts, samples, travel funds, consulting, and research.³⁰

■ **Group-purchasing organizations.** The majority of U.S. hospitals belong to GPOs, which are used to add efficiencies in the PPI arena through contracting assistance and value analysis.³¹ GPOs work with hospital members during periods of contracting to assess new products and track emerging technologies.³² Despite this, between periods of contract renewal, new products may be introduced at the bedside and avoid the purview of the GPO or hospital department.

Although the major GPOs have improved their data systems, data on implants are fragmented because of inconsistent approaches to price metrics, utilization, and outcomes across organizations.³³ Nondisclosure clauses block the availability of data to hospitals, regardless of GPO membership.³⁴ As individual systems engage in non-GPO purchasing, amassing data becomes even more difficult.

■ **Payers.** Medicare's focus has traditionally been on reimbursement at initial entry into the marketplace, followed by evaluation and adjustment of reimbursement rates based on clinical and cost experience.³⁵ Implant reimbursement from Medicare is bundled within a DRG payment. This places financial risk for the implant on the hospital and puts the hospital in charge of creating incentives for cost containment.

Hospitals are often successful in negotiating implant "carve-outs" with private insurers, which pay for implant costs separately from the per diem or percentage-of-charges reimbursement contract. Although the payer bears the financial risk for the cost of the implant, the payer lacks input on the hospital's choice of implants or supplier-contracting strategies.

Private insurers frequently assess evidence surrounding new technologies but infrequently negotiate with implant makers regarding price.³⁶ Private insurers, such as UnitedHealthcare, are increasingly investing resources for hospital collaboration, to gain insight into the clinical process via data and to develop incentives for higher-quality care, which has been linked with lower overall costs.³⁷

Evidence-Based Medicine In Orthopedics

Data on long-term outcomes for implants have not been uniformly collected and amassed in a central location in the United States. This multifaceted problem includes lack of a central evaluative body for data and medico-legal, privacy, and funding factors precluding formation of a national joint registry.

Higher-level evidence, such as that from randomized clinical trials (RCTs), has been less frequent in orthopedics than in some other areas of medicine.³⁸ This can be attributed to ethical dilemmas in randomizing patients to different procedures, variability in surgical techniques requiring ability to modify clinical choices intra-operatively, challenges in blinding, and expense of RCTs for procedures that measure their outcomes over decades.³⁹ Per William Obremskey and colleagues, level IV evidence (case series, case-control study, poor reference standard, or no sensitivity analysis) is the most common level of evidence in research studies in orthopedics. A minority of studies met criteria for level I evidence, including high-quality RCTs.⁴⁰ Because of a lack of national data, hospitals, payers, and GPOs have often worked independently rather than collaboratively to amass data.

Four Case Studies Of Emerging Hospital Strategies

Systematic analysis of PPI management and stakeholder relationships across the health care value chain is an important area that has not been extensively researched. Recent analysis revealed that some hospitals are engaging in PPI management through higher-level data analysis, standing VAT efforts, physician alignment efforts, and capitated contracting.⁴¹ Further building on this research, hospital systems engaged in unique practices for PPI management were studied. Systems were identified by the board of the Health Sector Supply Chain Research Consortium, School of Health Management and Policy, Arizona State University, on the basis of reputation gained through success and unique practices for PPI management. Researchers conducted site visits of identified organizations, which were then brought together in spring 2008 for a conference to discuss their efforts (described below). Assessment of the prevalence, success, and facilitators of the identified strategies among a larger number of hospitals was not done in this initial study but is planned in follow-up.

■ **Physician alignment and savings.** HCA-West Florida (HCA-WF) is part of a network of fifteen affiliated hospitals and six surgical centers that participate in HealthTrust GPO. Wanting to build physician alignment and achieve savings, HCA-WF launched an “internal sales force” initiative led and staffed by former supplier representatives who support working relationships among hospitals, physicians, and their office staffs. The strategy focuses on increasing volume and efficiencies in specific clinical service lines, including orthopedics.

Team members evaluate efficiency in the operating room and inpatient service, help identify problems, and facilitate change. The physician gains a voice in the

hospital, identifies business opportunities, and increases volume of practice. The hospital increases volume of business, lowers costs, and develops a partnership with physicians and a competitive position. Overarching characteristics of the internal sales force are a strong understanding of what is valuable for orthopedic surgeons in their practice and the ability to recruit former implant sales representatives as team members.

■ **Procurement and sourcing.** New York–Presbyterian Hospital (NYP) in New York City includes five hospitals—two tertiary care hospitals, a community hospital, a children’s hospital, and a psychiatric hospital—and is affiliated with two medical schools. NYP has developed a procurement and strategic sourcing team with product-line specialization. Its process involves disciplined engagement of physicians with fact-based information pertaining to costs and use.

The team (composed of a physician leader and managers with strong business backgrounds) uses a toolbox that includes counterdetailing, “crosswalks,” and scenario-based sourcing. In counterdetailing, a practice that initially started with pharmaceuticals as managed care companies pushed generics, the team provides publicly available data on product pricing and supplier profit margins to counter the information provided by suppliers.⁴² “Crosswalks,” which are included in requests for proposals (RFPs), are constructs that compare different supplier prices for clinically similar items. In scenario-based sourcing, different scenarios are incorporated into the RFP, which requires vendors to bid on different outcomes.

NYP’s approach is very data-driven, maintains business-style professionalism, and focuses on physicians as clinical partners. Similar to the HCA-WF strategy, the NYP effort thrives from strong leadership and administrative support, successful use of data, and a high level of respect and accountability in relationships with physicians.

■ **Group purchasing.** Sisters of Mercy Health System (SM) is an integrated delivery network that has developed its own group-purchasing effort (Resources Optimization and Innovation, or ROi), distribution system, and performance consulting competency to serve eighteen acute care hospitals, two cardiac hospitals, and managed care organizations in Arkansas, Kansas, Missouri, and Oklahoma. ROi/SM strives to develop sustainable partnerships with physicians practicing in the system.

ROi/SM’s total joint initiative is clinically integrated, data-driven, and collaborative. Strategies used in contracting include percentage off list price, pricing caps, risk sharing, vendor consolidation, and reimbursement ratios. The initiative has had estimated cost savings of \$1 million. Valuable lessons learned include the following: vendor compression saves money and reduces variability; the success of a strategy is dependent on physicians’ buy-in; and physician leadership leads to greater success. ROi/SM’s uniqueness is attributable to its efforts to bring together a wide variety of supply chain–management functions under its own roof.

■ **Supply-chain strategies.** Nebraska Orthopaedic Hospital (NOH), an acute care orthopedic specialty hospital located in Omaha, is a joint venture between Ne-

braska Medical Center and a formalized group of orthopedic surgeons. Supply-chain strategies include dual-source contracts for total joints with required 90 percent compliance, use of on-site vendor representatives to encourage on-contract product usage, pricing caps for basic implants, consistent data-driven meetings with physicians, and robust use of information technology (IT). NOH limits the number of vendors and carries no inventory. These strategies have resulted in average supply cost for a total knee replacement at NOH to be approximately half that of other area institutions with similar volumes.

Similar to the previous cases, NOH efforts thrive because of strong administrative support and involvement, focus on the physician as customer, and data-driven decisions. The strategies are enabled through a focused approach as a specialty hospital and its joint-venture status with an elite academic medical center.

Policy Recommendations

This detailed analysis and discussion of the economic issues and relational factors surrounding implants identifies areas of concern. Costs for implants are high, yet there is a disconnect between stakeholders surrounding these costs because of differing priorities and incentives. Differences in accountability are complicated by the lack of comprehensive, easily accessible, and high-quality clinical and cost data. A lack of transparency prevails for both prices and relationships.

The four case studies presented here are addressing these challenges by the development of robust strategies to forge relationships with physicians, amass data, and engage implant vendors. These are important models from which other systems can learn and possibly emulate; however, not all systems have the resources required to put forth such efforts.

If demand for replacement surgeries escalates as projected, costs for Medicare and other payers go up in response, and costs for hospitals continue to outpace reimbursements, these identified areas of concern could prove a detriment to overall welfare of the U.S. population. In the context of these present issues and future projections, we put forth the following policy recommendations.

■ **A centralized council.** Such a council would (1) perform systematic reviews of existing research, (2) perform technology assessment, (3) focus on clinical evidence and cost-effectiveness data, (4) identify gaps in knowledge, (5) provide information in an easily accessible database, and (6) provide continuous assessment.

A number of U.S. public and private agencies currently perform some of these tasks, including the Agency for Healthcare Research and Quality's (AHRQ's) Evidence-Based Practice Centers (EPCs), Hayes Inc., ECRI Institute, Tufts Medical Center's Cost-Effectiveness Analysis Registry, the Blue Cross Blue Shield Technology Evaluation Center (TEC), and the HMO Research Network.⁴³ One entity does not perform all tasks, nor are data easily accessible in every case.

A Center for Comparativeness Effectiveness has been debated, and funding was included in HR 3162, passed by the U.S. House of Representatives in 2007.⁴⁴ This

center would assess the clinical effectiveness and cost-effectiveness of medical treatments and procedures, perform systematic reviews of existing research, perform data review of medical records and administrative data, and fund prospective trials to fill in knowledge gaps.⁴⁵ Much discussion has centered on the governance and funding of this center. Criticisms have surrounded the accuracy of evaluation and the effect on coverage of medical treatments.⁴⁶ The time frame to obtain legislative approval and for the center to commence business is unknown.

The U.K. National Institute for Health and Clinical Excellence (NICE) performs systematic reviews of research, combines this with models of cost-effectiveness, and produces appraisals and guidelines for usage.⁴⁷ NICE tracked the use of different hip prostheses and put forth guidelines in 2000. Follow-up survey data indicated a reduction in the percentage of physicians using implants without the support of published evidence.⁴⁸

Dedicated funding from AHRQ to an EPC appears to be the most practical resource to use in obtaining the data for a centralized council, as detailed above. AHRQ's Technology Assessment Program 2006 Horizon Scan on Hip Replacement Surgery, performed by an EPC, provided a comprehensive evaluation of total hip replacements.⁴⁹ This excellent effort could be used as a model for a continuous effort but would need to be expanded to include cost-effectiveness information and other areas in orthopedics such as total knee replacements.

■ **A National Joint Registry.** Implant usage, outcomes, and longevity would be tracked via this registry. Long-term outcomes data would be amassed to evaluate the comparative effectiveness of various orthopedic implants.

The Swedish Total Hip Replacement Register has been a model for joint registries in other countries, and its success has been well documented. By 2000, six hip implants captured 70 percent of the market, with a nine-to-ten-year survival rate of 93–98.3 percent. Register data showed a higher revision burden for uncemented hips between 1979 and 2000, which led to practice changes by physicians. Estimated cost savings attributed to reduction of the revision burden were US\$140 million for a ten-year period.⁵⁰ The register has influenced surgical technique, implant choices, and outcomes. Also, Sweden's revision burden is 7 percent, compared to a revision burden of 18 percent in the United States.⁵¹

Kaiser Permanente developed a national total joint replacement registry in 2001. Data from this registry have shown a 10 percent difference in revision rates between partial and total knee replacements, leading to reduction in partial knee replacements and savings of \$550,000, and they identified an uncemented total knee technique that led to higher revision rates, knowledge of which led to reduction in the use of this technique.⁵²

Formation of a national joint replacement registry in the United States has been an ongoing effort through the American Association of Orthopedic Surgeons (AAOS) for more than ten years. Numerous difficulties have been encountered, including issues of information privacy, protection against misuse of information for

litigation, questions of ownership and management of data, enforcement of data reporting, and funding. Recent legislation regarding the formation of Patient Safety Organizations intended to safeguard information collected for quality improvement purposes is a positive development in the efforts to form a U.S. joint replacement registry.⁵³

■ **A National Implant Price Registry.** Increased transparency of information related to price would allow hospitals, payers, and ultimately patients to make better-informed, value-based decisions. In October 2007 the Medical Device Pricing Transparency Act of 2007 (S 2221) was introduced in the U.S. Senate. The bill would require manufacturers to report average and median selling prices of all implantable devices. Required quarterly reports from manufacturers on sales price data would need to include volume discounts, cash discounts, chargebacks, rebates, and any other discounts. The bill has been referred to the Committee on Finance.⁵⁴

Hospitals, in the absence of mandated transparency, will continue to work with their GPOs and consultants to amass price information and leverage suppliers to reduce costs. However, with custom contracting and database information lacking discounts and rebates, an information vacuum is likely to persist.

■ **Increased financial incentives for stakeholders to collaborate.** This would encourage greater collaboration between hospitals and physicians in evaluating the comparative effectiveness of implants. Formal gainsharing arrangements between hospitals and physicians have been used in cardiology and cardiac surgery. A recent study on gainsharing in cardiology, funded by the Health Sector Supply Chain Research Consortium, found that gainsharing hospitals reduced costs by 7.4 percent mainly as a result of lower prices.⁵⁵ Gainsharing could be a useful incentive in orthopedic surgery. The main obstacle to date has been strict regulations and difficulty in obtaining a favorable Office of Inspector General (OIG) opinion. The Centers for Medicare and Medicaid Services (CMS) recently proposed demonstration projects related to implant replacement procedures that may provide more support for gainsharing and potentially lead to relaxed regulations.⁵⁶ An additional incentive area is increased reimbursement rates for hospitals and physicians who actively collaborate in comparative effectiveness evaluations of implants.

Challenges, Projections, And Solutions

Our focused and detailed look at the issues, relationships, emerging hospital strategies, and policy needs for implants demonstrates the complexities. Challenges stem from cost and reimbursement issues, different levels of stakeholder accountability, stakeholder relationships, lack of comparative effectiveness data from a national source, and lack of price transparency. Superimposed on these issues are projections for substantial future demand for hip and knee replacements.

Despite robust efforts at the hospital and system level, it seems clear that a national focus is needed, given the population-level implications of demand and cost for hip and knee replacements. Sweden's national joint replacement registry has

demonstrated the success of a registry for providing data and affecting clinical choices, revision burden, and costs. NICE has shown the ability of a centralized body to amass data, determine cost-effectiveness, and influence knowledge via guidelines. These models provide evidence of success for U.S. efforts in the same areas.

Lack of price transparency in the implant market has affected hospitals' costs for implants and their ability to collaborate with physicians surrounding implants. New York–Presbyterian's use of counterdetailing and “crosswalks” directly addresses this difficulty. As we face increased costs in the future, price transparency is important to facilitate comparative analysis.

Incentives have been part of the efforts at HCA–West Florida, New York–Presbyterian, Sisters of Mercy, and Nebraska Orthopaedic. Their focus on providing value to physicians and prioritizing the hospital-physician relationship has been an important component of their success for cost savings and getting physicians involved. Recommended policies for relaxed regulation for gainsharing and increased reimbursements to incentivize collaboration surrounding hip and knee implants could further augment this movement at the hospital level.

Hip and knee replacement surgery will continue to provide valuable improvements in quality of life for patients who suffer from disabling arthritic conditions of the hip and knee. However, it is imperative that collaborative efforts be made to improve the availability and transparency of data to sustain the long-term financial viability of these procedures.

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NOTES

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