Health Policy and Financial Issues Related to New Total Knee Arthroplasty Technology

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Summary: As demand for knee replacement surgery continues to rise, new technologies continue to be introduced with the hopes of improving total knee arthroplasty outcomes. As new value based health care models are introduced, the ability to pay for these new technologies will likely be impacted. Because of past implant failures and limitations, it will be important for providers to use registries to evaluate both the safety and outcomes of new knee arthroplasty designs.

Key Words: total knee arthroplasty—technology—future issues—health policy.

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Total knee arthroplasty is one of the most commonly performed operations in the United States. In 2014, Medicare paid for more than 400,000 inpatient knee replacement surgeries with total hospital costs of $7 billion.[1] As the number of procedures continues to rise, the importance of finding effective strategies to ensure the appropriate use of surgery and manage costs will continue to be at the forefront of policy and financial issues.

Most physicians in their current practice tend to choose a particular knee implant based on their familiarity with or loyalty to a certain device and/or manufacturer.[2] In contrast, patients want the newest and best implants. When patients were asked if they would be willing to pay out of pocket for a higher than standard of care prosthesis, 86% replied yes.[3] Patients preferred an innovative, nonstandard implant even if the cost were higher.[3] The general perception that newer is better is a conversation that surgeons will continue to have with their patients. However, as recent innovations have shown, newer is not always better.

Over the last 10 years implant manufactures have introduced innovative knee arthroplasty design features such as targeting high flexion by improving implant kinematics, gender-specific knee replacements, and bicruciate-stabilized implants. Disappointingly, studies of these innovations have failed to show any significant improvement in motion, survivorship or clinical outcomes compared with standard total knee arthroplasty designs.[4–7] The 2010 recall and widespread failure of mental-on-metal hip implants has heightened the awareness and importance of evaluating new technology safety in a more systematic and purposeful way before allowing widespread adoption.

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HEALTH POLICY TRENDS

Value-based Health Care

Value-based health care is emerging as an important driver in health care delivery and payment reforms. Michael Porter,[8] a renowned health economist from Harvard Business School, has repeatedly argued that "value in health care is measured by the outcomes achieved—relative to the cost." With the widespread acceptance of the value framework into health care delivery, orthopedic surgeons will need to consider both outcomes and costs in their clinical decision making. Bundled payment models for total joint replacements are an early implementation of value-driven health care. These models have required institutions to coordinate and manage care across the continuum, and accept responsibility for outcomes and costs across the full episode of care. In 2013, the Centers for Medicare and Medicaid Services (CMS) expanded the Bundled Payment for Care Improvement (BPCI) pilot to include acute and postacute care for 30 days. A majority of hospitals that participated in the BPCI pilot were able to reduce the overall cost per episode of care and a majority of cost savings were the result of lower prices paid per implant and decreased patient length of stay.[9] There was a 15.5% national reduction in price per implant and some institutions reported up to a 30% reduction.[10]

In 2016, due to the success of the BPCI pilot, CMS implemented a mandatory bundled payment program in 67 urban geographic areas called the Comprehensive Care for Joint Replacement Model (CJR). The goal of CJR is to encourage hospitals, physicians, and postacute care providers to work together to improve the quality and coordination of care through an expanded 90-day episode of care. The program aims to reduce the unnecessary variance in complication rates, utilization of postacute care, and overall costs across hospitals and geographic regions of the country. The program is designed to financially reward hospitals for providing cost-effective and high-quality care, while levying penalties for poor outcomes.[1] With the further expansion of bundled care models, implant manufacturers are likely to continue to see downward pressure on the cost of their implants. The ultimate question is whether pricing pressure will limit implant manufacturers' ability to deliver new and innovative products. Or, will the increased demand for knee arthroplasty implants offset the decreased margins manufacturers are experiencing and allow them to continue to invest in research and development. Although controversy remains over the future of mandatory versus voluntary bundled payment programs,[11] the US market seems to have adopted bundled payment programs, and the success of implant companies may be related to how they support these value-based changes.

Commoditization of Implants

In response to the expansion of bundled payment models and CMS's mandatory implementation of CJR, device companies are now offering low cost implants and business solutions to help hospitals and physicians transition to bundled

payment models. Many agree there are few clinical differences between the knee implant systems sold by manufacturers. In response to pricing pressures, Smith & Nephew's Syncera has plans to introduce a rep-less sales model that sells an older generation of Smith and Nephew's hip and knee implants to lower their selling, general and administrative expenses.[12] Through this model it is estimated their implants will be sold at a 30% discount.[12] Medtronic recently purchased Responsive Orthopedics, a maker of lower-cost hip and knee implants with plans to also introduce a low-cost knee and hip replacement system.[13] In response to CJR and the data collection necessary to implement the CJR program, some device manufactures have created care platforms such as Stryker's Joint COACH and Zimmer Biomet Signature Solutions to optimize patient coordination and outcomes data in a value-based health care environment.[13] Large implant companies have consolidated and focused on preoperative and postoperative care platforms which has given way for newcomers to launch low cost products. The large device manufacturers, who traditionally have been implant innovators, are likely to continue feeling price pressure and focus on providing new care segments to supplement their margins and hospital commitments. The question is whether they will lose focus on investing in future implant innovation.

FINANCIAL ISSUES

Lack of Price Transparency

Orthopedic surgeons are the gatekeepers to providing orthopedic care. However, it can be difficult for surgeons to access information about the price of the implants they use, even though orthopedic implants can represent a significant portion of the procedural cost of care.[14] A recent survey found attending physicians correctly estimated the cost of the device only 21% of the time.[15] The lack of price transparency limits competition and patients' and surgeons' ability to make educated health care decisions. Without mandated price transparency, hospitals will continue to compile pricing benchmark data which lacks the discounts and rebates given to large hospital systems. This limits the knowledge of the true price of an implant which impacts a surgeon's ability to make an economical decision. In 2007, The Medical Device Pricing Transparency Act was introduced but not enacted, due to device manufacturer sponsored reports that concluded that price disclosure could harm consumers more than help.[16] Price transparency in its current form has not been found useful to patients themselves,[17] but price transparency could better align physician-hospital relationships to lower hospital costs.[18]

Large Capital Investments

New technologies require large capital investments. It has been suggested that implant manufacturers charge higher prices on current devices in order to continue to support research and development to produce innovative improvements for future devices that will improve patient care. Critics believe this is largely a misnomer, as many manufactures simply tweak their current products and instrumentation in the name of innovation. Orthopedic device companies on average spend approximately 6% of revenue on research and development, which is far below the average for both the pharmaceutical and medical device industry.[19] Many have blamed the Affordable Care Act levy of 2.3% on all medical device revenue as a cause for the limited investment and output in medical technology and recent job losses reported in the industry.[20,21]

Medical devices in the United States reach market primarily through 1 of 3 tracks: Premarket Notification [commonly known as 510(k) Clearance], Humanitarian Device Exemption, and Premarket Approval (PMA).[22] These regulatory processes are overseen by the Center for Devices and Radiological Health within the US Food and Drug Administration (FDA).[23] PMA is the most rigorous process, reserved for high-risk devices, including those representing a completely novel design.[24] Most orthopedic implants received FDA clearance through demonstrating safety and efficacy equivalent to that of devices already in use and are approved under 510(k) clearance. This regulatory pathway takes only 6 to 9 months.[25] From 2003 through 2013, PMA notifications declined by $>30\%$ and submissions for 510(k) increased by $\sim 10\%$ yearly, indicating a shift from new innovative designs to simple line extension and incremental changes.[26] It is believed that the increasingly burdensome regulatory landscape and the fact that current implants have such good results and longevity make it difficult to truly innovate.[26] Of 5 new implants introduced for both knee and hip arthroplasty, none of them was found to be better than the devices already in use.[27,28] The longevity of traditional implants, an unpredictable regulatory climate from the FDA, longer regulatory process to market, and complex value-based reimbursement initiatives have made investing in medical devices higher risk.[29] This higher risk with limited reward category has resulted in a decline in medical device financing. In 2016, only 5% of venture investment went into medical device companies, a decrease of $>50\%$ compared with 2010.[29] Innovation requires truly new ideas and deep pockets to persevere through the regulatory hurdles and long waits to market.

ISSUES FOR THE FUTURE

Improve the Quality of Implant Studies

New technologies are being introduced to the commercial market without high quality evidence that these implant designs are beneficial over existing and safe alternatives.[27] Barker and colleagues utilized the FDA's public database to review the methodology of clinical studies used to approve high-risk orthopedic devices. The study found that 90% of high-risk orthopedic devices were approved with one supporting clinical study, including one device that was approved on the basis of a single-center retrospective case series of 53 patients. Another device was approved from a retrospective case series from a single surgeon practicing outside the United States. These limited study designs raise important questions, especially about the generalizability of their results.[30] PMA is the most rigorous FDA process through which high-risk devices reach the market. However, the clinical trials used by the FDA to approve such devices demonstrate marked variability in the reporting and strength of methodology.[30] In addition, when orthopedic devices go through the PMA process, many of the devices undergo postmarket modification and shift away from the initially tested designs.[31]

National Registries: Evaluate New Technology

National registries, including the American Joint Replacement Registry, provide the infrastructure and postmarket surveillance for total knee arthroplasty technologies to be introduced safely and quickly, and to identify poor technologies that need to be discontinued. Because of the fact that knee arthroplasty has such a low revision rate ($\sim 5\%$ at 10 years), to have an 80% chance of detecting a 30% difference in revision rate, almost 4000 patients would need to be enrolled

into a randomized controlled trial.[32] Such a trial would be prohibitively expensive and laborious, thus registries can serve as a more practical and simpler method to evaluate these differences. Registries offer assessment of devices in the real-world setting compared with the controlled setting utilized in studies undertaken for device approval. Registries also provide information on variables such as technique, surgeon, hospital, and patient characteristics that could impact the use of a medical device.

There are multiple examples where registries have provided important implant information.[33] The United Kingdom National Joint Registry helped identify the increased revision rates of metal-on-metal hip replacements, resulting in the British Hip Society being the first to provide their concern and recommendations.[34,35] The Finnish registry found that recently introduced knee implant systems had higher revision rates due to model-specific learning curves for surgeons.[36]

Large national arthroplasty registries are imperative to review and evaluate new and existing technologies over time as technologies are introduced. Only registry data combined with functional and outcome information offer clinicians and engineers the power to sort out real differences between implant designs and flaws.[27] Because of widespread failures seen from metal-on-metal hip implants, adoption and widespread use of new implants and technology requires a thorough evaluation by surgeons and regulators. National registries create the best source of information to assess the performance of these new technologies. New devices that do not have a well-established safety profile should not be exposed to a large number of patients without having a clear and stepwise method to introduce these new technologies. Although it is unclear if the failure of metal-on-metal hip replacements was an isolated event or a sign of a systemic problem in the industry,[37] it serves as a reminder that new technology can cause harm and needs to be carefully evaluated.

FUTURE CHALLENGES AND SOLUTIONS

Total knee arthroplasty patients today are younger and more active. As a result, their expectations are higher, and they put greater demands on their knee implants. Improving knee implant designs to achieve superior outcomes and longevity is needed to meet these demands. We need to advance technology with new designs and materials. However, all stakeholders must invest in careful evidence-based evaluation and promotion of new devices. The goal should not be to accept the status quo, but to continue to improve, learning from mistakes of the past. Introduction of new knee arthroplasty technologies requires a close relationship between surgeons, regulators, industry and scientists. To justify the increased cost for a new implant, the implant needs to demonstrated improved function and longevity. We should continue to strive to improve total knee arthroplasty outcomes, including developing novel implants that have the potential to improve patient function and reduce implant failure rates. If a new technology arrives that improves patient outcomes above the current standards, it will be widely adopted and extremely profitable.

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