The Role of Value-Based Implants in Orthopedic Trauma

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KEYWORDS

• Value-based implants • Generic implants • Health care finance • Health care economics

KEY POINTS

- In this era of rapidly rising health care costs, it is the physician's moral and ethical responsibility to pursue value-based care options in orthopedics.
- Value-based and generic pharmaceutical options are widely accepted alternatives that have saved the health care system massive amounts of money with similar outcomes.
- Trauma patients are an underinsured patient population, and value-based care models involving care plans and decreased implant costs are needed to allow for the provision of quality care.
- Current research and US Food and Drug Administration regulations demonstrate that value-based implants are clinically equivalent to conventional implants; the only difference is cost.
- Gain sharing, comanagement, and bundled payment initiatives provide surgeons with incentive toward value-based care.

INTRODUCTION

Health care costs in the United States continue to increase, now accounting for more than $3.3 trillion, consuming 17.9% of the gross domestic product.[1] National health care spending is projected to grow at an average rate of 5.6% per year for 2016 to 2025, growing 1.2% points faster than the gross domestic product, resulting in continued escalation toward an unsustainable dollar amount.[2] Means of cost containment are being increasingly introduced on multiple levels by all parties. These include diagnosis-related group-based reimbursement to hospitals, bundling of payments for certain episodes of care, hospital use of matrix implant pricing, and reduced reimbursement for physicians.

Physicians, including orthopedic surgeons, have historically been poor stewards of cost containment and resource management. Several studies demonstrate that orthopedic surgeons often inaccurately estimate the cost of their implants and tend to underestimate the cost rather than overestimate.[3–5] New technology is commonly adopted by surgeons without the need and without strong evidence supporting improved outcomes. Historically, physician participation in hospital implant selection, screening, and pricing was uncommon. This allowed implant costs to increase unnecessarily exponentially. Failure to adhere to accepted preoperative screening guidelines and the practice of defensive medicine in orthopedic trauma are further examples of poor cost control by the medical community.[6–8] As costs continue to increase, so has transparency of pricing and cost increases, resulting in mounting pressure for physicians to be better stewards of the health care dollar.[9]

DISCUSSION

The total US orthopedic trauma implant market is estimated to be valued over $5.3 billion.[10] Implant costs are still the highest expense in

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the operating room budget. Curtailing implant costs remains one the most straightforward ways to decrease costs in orthopedic trauma surgery. Much as generic alternatives to prescription medications become available as patents on existing brand medications expire, several orthopedic implant companies have emerged to distribute value-based orthopedic implants.

Value-Based Implant Background

In response to the rising economic pressure on the delivery of orthopedic care, several companies have entered the orthopedic implant market deploying various models that lower the cost of implant usage. These include decreasing the cost of implants themselves, eliminating sales representatives who utilize 42% of conventional implant company revenue, and utilizing single-use kits. These kits include all instrumentation, disposables, and implants required for a single small fragment fracture case. In this model, these vendors claim savings by eliminating the need for decontamination and sterilization of instrument and implant trays. The combination of eliminating sales representatives and utilizing value-based implants has the greatest potential to decrease costs.

Because of the massive financial impact value-based implants could have on the market, significant efforts are being undertaken by conventional companies to create an illusion of inferiority. Such techniques were attempted in the pharmaceutical industry and failed due to the US Food And Drug Administration (FDA) approval system. Like pharmaceuticals, the approval process to make and sell implants in the United States, outlined in section 510(k) of the Federal Food, Drug and Cosmetic Act, is the same for all. Vendors are required to submit criteria proving the likeness of its market-ready implant to preceding implants offered in the market by any vendor. Biomechanical testing data and implant design files are submitted for review by the FDA, and all vendors are held to the same standards by which the submitted data are measured. The FDA then provides the vendor with a letter stating that its findings indicate the device is substantially equivalent to the preceding device. The nature of the 510(k)-approval process highlights the fact that all implants brought to market in this fashion are generic, regardless of vendor.

It is also important to note the use of contract manufacturing in orthopedic implants. The entire US implant industry relies heavily on this process, which is an outsourced means of production that lowers manufacturing costs and quickens production. In the United States, contract manufacturing companies produce both brand name and value-based implants on the same machines, from the same medical-grade materials, and put them through the same quality assurance checks. Thus, both value-based and conventional implants are manufactured and produced in the same factories in the same way by the same people. Value-based implant companies now produce a variety of orthopedic trauma implants including cannulated screw systems, intramedullary nails, and locking plate systems.

Scientific Support

Hundreds of articles demonstrating the clinical equivalence of generic medications can be found in the literature; however, there is a paucity of literature comparing value-based implants with conventional implants. Waddell and colleagues[11] published a clinical trial involving 150 patients looking at generic total hip implants in Canada. Patients were followed for at least 2 years. These authors found no increased complication rates and general improvement in Harris hip scores with the use of generic implants. Another paper by Althausen and colleagues[12] evaluated the clinical and economic benefits of generic 7.3 mm cannulated screw use for the treatment of femoral neck fractures and percutaneous sacroiliac fixation. These authors demonstrated a 70% reduction in implant costs with no difference in the clinical outcomes of infection, nonunion, need for revision surgery, or mortality.

A third study by McPhillamy and colleagues evaluated generic locking plate utilization in a similar study. Operatively treated fractures evaluated included clavicle, proximal humerus, distal radius, proximal tibia, distal tibia pilon, and ankle fractures. These authors found a 56% reduction in implant costs with no differences in clinical outcomes of malunion, nonunion, implant failure, infection, and symptomatic implants requiring removal. The use of generic implants in this study resulted in an average cost savings of $1197 per case and a total amount saved of $458,080 over the study period.[13] Newer generic implant designs, such as intramedullary nails and external fixation, continue to be released and have the potential for significant cost savings as well; however, these implants have not been used long enough to study effectively at the current time.

Barriers to Value-Based Implant Utilization

Despite the economic pressures placed on care of the orthopedic trauma patient, biomechanical equivalence of value-based implants and