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In Orthopedic Trauma, the Importance of Value-based Implants

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Perspective

Health-care costs in the United States have continued to rise, currently totaling more than $3.3 trillion and accounting for 17.9% of the country's GDP. From 2016 to 2025, national health-care spending is expected to climb at a 5.6 percent annual rate, 1.2 percent faster than the gross domestic product, resulting in steady escalation toward an unsustainable monetary level. All parties are gradually introducing cost-cutting measures on multiple points. These include diagnosis-related group-based compensation to hospitals, payment bundling for some episodes of care, hospital usage of matrix implant pricing, and physician reimbursement cuts. Physicians, notably orthopaedic surgeons, have a long history of being poor cost-cutters and resource managers. Several research show that orthopaedic surgeons frequently underestimate rather than exaggerate the cost of their implants, according to several studies. Surgeons often use new technology without a need for it and without convincing proof that it improves results. Physician involvement in hospital implant selection, screening, and pricing has been unusual in the past. This resulted in an excessively exponential increase in implant costs. Failure to follow acknowledged preoperative screening standards and the use of defensive medicine in orthopaedic trauma are two other examples of the medical community's inadequate cost control. As expenses rise, so does transparency of pricing and cost increases, putting increasing pressure on doctors to be better stewards of the health-care dollar.

In the United States, the overall market for orthopaedic trauma implants is expected to be worth more than $5.3 billion. In the operating room budget, implant prices are still the most expensive item. One of the easiest methods to cut costs in orthopaedic trauma surgery is to reduce implant costs. Several orthopaedic implant companies have sprung up to distribute value-based orthopaedic implants, much like generic alternatives to prescription pharmaceuticals become accessible as patents on existing brand medications expire. Several businesses have entered the orthopaedic implant industry, deploying various models that minimise the cost of implant usage, in response to increased economic pressure on the delivery of physical care. These include lowering the cost of implants, eliminating sales reps, who account for 42% of traditional implant revenue, and using single-use kits. All of the instruments, disposables, and implants needed for a single small fragment fracture case are included among the kits. These vendors say that this technique saves money by eliminating the requirement for instrument and implant trays to be decontaminated and sterilised. The most cost-cutting combination is to eliminate sales personnel and use value-based implants.

Value-based implant background

The FDA receives biomechanical testing data and implant design files for assessment, and all vendors are held to the same criteria when evaluating the data. The FDA then sends the vendor a letter stating that the device is substantially equivalent to the previous device based on its findings. The 510(k) approval process emphasises the fact that all implants brought to market in this manner, regardless of vendor, are generic. Because of the tremendous financial impact that value-based implants could have on the market, established corporations are working hard to create the illusion of inferiority. Such strategies have been tried in the pharmaceutical sector but have failed due to the FDA approval system in the United States. The approval process for manufacturing and selling implants in the United States is the same as it is for medicines, as specified in section 510(k) of the Federal Food, Drug, and Cosmetic Act. Vendors must give criteria demonstrating the similarity of their market-ready implant to previous implants available on the market from any vendor.

The FDA receives biomechanical testing data and implant design files for evaluation. It's also worth noting that orthopaedic implants involve contract manufacturing. This approach, which is an outsourced production method that decreases manufacturing costs and speeds up production, is heavily used by the whole US implant business. Contract manufacturing businesses in the United States make both brand-name and value-based implants on the same equipment, using the same medical-grade supplies and subjecting them to the same quality assurance inspections. As a result, both value-based and traditional implants are created and produced by the same individuals in the same factories. Cannulated screw systems, intramedullary nails, and locking plate systems are among the orthopaedic trauma implants produced by value-based implant firms.

Scientific support

There are hundreds of studies in the literature confirming the clinical equivalency of generic drugs; nevertheless, there is a scarcity of literature comparing value-based implants to conventional implants. In Canada, Waddell and colleagues presented the results of a clinical trial including 150 patients using generic complete hip implants. The patients were followed for a minimum of two years. With the use of generic implants, these researchers discovered no higher complication rates and a general improvement in Harris hip scores. Althausen and colleagues looked at the clinical and financial benefits of using a generic 7.3 mm cannulated screw for femoral neck fractures and percutaneous sacroiliac fixation. These researchers found that implant expenses were reduced by 70% although infection, nonunion, the requirement for revision surgery, and death remained unchanged. In a third study, McPhillamy and colleagues looked at how generic locking plates were used. The clavicle, proximal humerus, distal radius, proximal tibia, distal tibia pilon, and ankle fractures were all evaluated as surgically repaired fractures. These researchers discovered a 56% reduction in implant prices with no differences in clinical outcomes such as malunion, nonunion, implant failure, infection, or symptomatic implants that required removal. In this investigation, the use of generic implants resulted in an average cost savings of $1197 per case and a total savings of $458,080 throughout the course of the trial. Newer generic implant designs, such as intramedullary nails and external fixation, are now being released, and they have the potential to save a lot of money; unfortunately, these implants haven't been studied well yet [1-5].

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