Arthroplasty Today 5 (2019) 256–259

Contents lists available at ScienceDirect

Arthroplasty Today

journal homepage: http://www.arthroplastytoday.org/

Viewpoint

Policy and Ethical Considerations for Widespread Utilization of Generic Orthopedic Implants

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ARTICLE INFO

Keywords:
Implants
Ethics
Orthopedic surgery
Health economics
Health policy

Introduction

In 2015, the United States spent $3.2 trillion on healthcare, representing 18% of the nation's gross domestic product [1]. As prices continue to climb, physicians, healthcare policymakers, and industry leaders alike have sought varied means to lower costs while maintaining the quality of care. Coverage expansion, shifts toward bundled care payments, and the implementation of Medicare Payment Reform (Medicare Access and Children's Health Insurance Program Reauthorization Act of 2015 [MACRA]) are indicative of shifting dynamics in the American healthcare system prioritizing outcomes, value, and cost-containment over the fee-for-service model [2,3].

Orthopedic implant expenditures are considerable in the overall cost of care for surgical patients. The cost of total joint arthroplasty implants between 1996 and 2006 increased an estimated 130%. Implant and medical device costs comprise up to 60% of hospital reimbursements for primary procedures [4]. Most implants are proprietary in nature and vary substantially in their price and features depending on the industry manufacturer [5-7].

Control of implant costs is thus a necessary focus for cost containment in orthopedic surgery. To that end, as patents on many brand name implants begin to expire, "generic" implants present a unique opportunity to improve the value of orthopedic care. Although generic drugs have been used for decades in the pharmaceutical industry, the use of generic implants has only recently been considered in the field of orthopedic surgery [8-10]. In the pharmaceutical sector, an estimated $33 billion has been saved by Medicare in the United States through utilization of generic medications [11]. There could be potential for an analogous substantial reduction in healthcare expenditures via the use of generic orthopedic implants.

There is some literature describing the favorable economic possibilities for use of generic orthopedic implants [9,10,12]. However, the ethical issues, policy implications, and potential unanticipated consequences of such a paradigm shift have not been investigated. This article discusses the pros and cons of generic implant usage from economic, clinical, and ethical perspectives.

Arguments in favor of generic implant usage

Autonomy, stakeholders, and the ethics of evolving market forces

The use of orthopedic implants intertwines the incentives, interests, and objectives of 3 key stakeholders: (1) patients; (2) surgeons, and (3) orthopedic device manufacturers (ODMs). The foremost mutual interest for all 3 parties ought to be the best possible patient outcomes. However, the fiduciary responsibility ODMs have to investors produces potential conflicts for patient care. In the United States, there is a trend toward corporate consolidation. This trend is observed among healthcare insurance companies, hospital systems, as well as medical device vendors [13]. These mergers and the resulting contraction of provider options may undermine competitiveness in the healthcare market and potentially inflate prices. The consolidation of ODMs transfers price-negotiating power to vendors and away from physicians, hospitals, and patients who are left with fewer options. Parallel trends have been evident in the pharmaceutical market where prices set by pharmaceutical companies have been shown to negatively impact patient access to lifesaving drugs. Profit margins increase when vendors negotiate with payors and insurers to

One or more of the authors of this paper have disclosed potential or pertinent conflicts of interest, which may include receipt of payment, either direct or indirect, institutional support, or association with an entity in the biomedical field which may be perceived to have potential conflict of interest with this work. For full disclosure statements refer to https://doi.org/10.1016/j.artd.2019.02.007.

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https://doi.org/10.1016/j.artd.2019.02.007

secure higher prices for implants. This results in direct and indirect financial cost to patients through out-of-pocket costs and insurance premiums [14].

The ethical principle of autonomy emphasizes a patient's right to make well-informed decisions for their own lives consistent with their values and is an integral component of clinical decision making [15]. Patient input into prosthesis choice and the price of orthopedic implants is mostly absent. This is in part due to a lack of technical knowledge necessary to understand the differences between implant types, and many patients defer decisions on medical devices to their surgeons. Although patient input into the technical aspects of prosthesis choice is unlikely, patient cost-sharing systems and increased price transparency paradigms have been advocated that could enable patient input into the process of prosthesis selection. A barrier to this transparency includes manufacturer-driven price confidentiality clauses. Price secrecy contributes to physician price insensitivity in addition to hindering patient autonomy and participation in implant price discussions [16].

The introduction of generic implants could change the dynamics of this market by increasing the available supply of implants and shifting this equilibrium of control toward surgeons and patients. Generic implant utilization could be coupled with price transparency initiatives to bolster competitive bidding, drive down costs in the healthcare system, and aid in eliminating the variability of implant costs. Simple awareness of implant price has been demonstrated to influence surgeons' choice, with many surgeons opting for lower priced models in the same implant class [17]. The inclusion of generic implants may thus enhance surgeon autonomy in dictating their surgical practice preferences. In a shared decision-making model, this increased autonomy extends to the patient and confers an added degree of choice to patients regarding the costs of their care [18].

Facilitating value and justice

Utilitarian theory is rooted in the concept that the most ethical course of action in a given situation produces the greatest benefit for the greatest number of persons. This theory of ethical reasoning, credited in its modern form to 19th century philosopher John Stuart Mills, dictates that it is permissible to supersede individual autonomy in favor of an action that produces a net good for society. In the absence of infinite resources, many health policy decisions require ethical reasoning that addresses the distribution of funding or resources in such a manner that the greatest benefit is achieved for the greatest number of people—sometimes at the expense of patients' and physicians' personal preferences for care [19]. Meanwhile, the principle of justice, as initially described by John Rawls, emphasizes distributive fairness to produce societal good, but includes the caveat that each individual "possesses an inviolability founded on justice that even the welfare of society as a whole cannot override" [20,21].

Although governmental institutions may be apt to make utilitarian decisions for the sake of net societal gain, individual physicians are bound to the principle of nonmaleficence—the responsibility to minimize harm to the individual patient to reach a beneficial outcome. In patient relationships, the physician ethos aligns more consistently with the principle of justice. These ethical principles can be applied to certain facets of the utilization of generic implants in orthopedic surgery.

The thrust of the argument for generic implants in orthopedic surgery relies on the potential to increase value, defined as quality/cost. The variability of costs associated with orthopedic implants is substantial. In a study by Bozic and Beringer, average prices for knee implants ranged from $1797 to $12,093. A similar variation in hip replacement implants from $2392 to $12,651 was noted [22]. The attributable variance in implant costs was primarily derived from characteristics independent of patient or hospital factors, suggesting that implant choice has a significant impact on these costs and in turn, the value of these surgeries [3]. Sales, marketing, and account management are estimated to comprise up to 40% of the cost of the implant [12]. Generic implants would ostensibly eliminate a substantial proportion of these expenditures.

Evidence for clinical and economic favorability of generic implants

If the quality of generic implants is equivalent to analogous brand implants and generic implants remain less expensive, the utilization of generic implants would add value to the field of orthopedic surgery. Although evidence supporting the safety of generic implants exists, equivalence is not yet well established across orthopedic subspecialty implant systems, and further rigorous research is required. A study by McPhillamy et al explored use of generic implants compared to conventional implants in 828 patients. The hospital realized a 56% reduction in implant costs and $458,080 in total savings for the study period and clinical outcomes were equivalent [9]. A retrospective study in 2014 by Althausen et al [10] similarly showed no differences in clinical outcomes for patients with femoral neck fractures or posterior pelvic ring injuries managed with generic implants compared to conventional implants and a 70% reduction in implant costs was observed.

Should additional comparative studies establish this equivalence in generic and brand name implants, the argument for value would be strengthened. When 2 treatment options achieve equivalent clinical outcomes, it is morally justified, or even obligatory, for physicians to advocate for utilization of the lower priced modality of treatment. This aligns with the aforementioned framework of utilitarian ethics, which postulates a commitment to maximizing the most benefit for the most people as well as the principle of justice. The argument that generic implant utilization satisfies the principle of justice would be particularly well supported in resource-limited environments where cost savings could be directed toward treating more patients, or to support initiatives that improve access to care. However, in order to ensure that cost savings were directed toward such initiatives, measures explicitly mandating appropriation of savings toward patients or access initiatives may be necessary.

A means to address local musculoskeletal surgical disease burden

The idea that physicians have a moral obligation to provide cost-conscious, high-value healthcare to their communities is gaining traction. Physicians who deliver cost-effective, evidence-based care to patients not only help contain untenable healthcare expenditures but also promote community health. Cost-conscious care can also enhance the fair allocation of health resources and can thus maintain the primacy of the patient's welfare [23].

For orthopedic surgeons, the wide variation in orthopedic implant prices has direct ethical implications for underserved populations. Underinsured and uninsured patients have been found to pay higher premiums and out-of-pocket expenditures for medical services [24]. This creates financial barriers to care for underserved patients who may exacerbate existing healthcare disparities. Expensive branded implants can affect care rationing when hospitals operate on a fixed budget. The inflation of the total cost of care also indirectly increases out-of-pocket patient spending. If generic implant utilization lowers costs of orthopedic surgical services in the United States, this could in turn lower

barriers to care for disenfranchised patients in keeping with the ethical principles of beneficence and justice. However, in order to accomplish such downstream effects, concerted regulation and oversight would be required to see these savings translate to benefits for underserved populations.

Eliminating conflicts of interest

There are several ethical concerns inherent in the relationship between surgeons and industry-linked ODMs. The potential for conflicts of interest and perverse financial incentives fostered by the relationship between ODMs and surgeons is well summarized by Lim and Aquino [25]. Many surgeons conduct research in collaboration with ODMs and consult for industry vendors. Physician input is integral to the design of clinically sound implants but also impacts the integrity of price negotiations. When a surgeon has a personal stake in a particular implant, there is a potential for selection bias. As many as 39% of surgeons report a conflict of interest [26,27]. Increased use of generic orthopedic implants has the potential to drastically alter this relationship between surgeons and ODMs. With the disentanglement of physician-industry relationships, bias could be minimized or eliminated. This would address a persistent ethical concern in the healthcare industry.

Arguments against generic implant usage

Unintended consequences for innovation and philanthropy

Value is enhanced not only by cost reduction but also through improvement in quality. Innovation for improvement in orthopedic devices and procedures produces a tremendous benefit for patients and thus can improve quality of care. Cost reduction enhances value, but this must be weighed against the potential to undermine incentives for ODMs to innovate and improve on existing proprietary implants. The cost and process for bringing a new medical device to the US market can be prohibitively expensive and time-consuming. Should the demand for branded orthopedic implants shrink in favor of generics, incentives for research innovation and development of implants would dwindle adversely affecting the future quality of patient care.

Historically, the partnership between ODMs and surgeons has resulted in innovative new prostheses and procedures, which have greatly benefitted patients. Ethical management of relationships between industry vendors and physicians is feasible and provides benefit to patients and health systems alike. In order to entice physician usage of their implants, many ODMs contribute significantly to graduate medical education and are engaged in humanitarian initiatives—producing a contribution to beneficence from the use of industry-sponsored implants. An unintended consequence of a shift toward generic implants and away from private vendors would be impeding industry-sponsored medical education and philanthropy.

Quality control, nonmaleficence, and health disparities

Patients may express preference for “higher end” implants; however, there is little evidence to suggest that there is substantial input from patients on the type of implants used during their surgery. In orthopedic trauma, notably emergent injury, patient autonomy in implant choice is difficult to accommodate explicitly. This shifts the focus to the forces external to the physician-patient relationship dictating the circumstances in which generic implants would be utilized.

In hospitals depending on federal financial support, budget restrictions could result in increased use of less expensive generic implants to remain financially solvent. This could result in generic implants being used disproportionately on low-income patients relying on Medicaid and minority patients—potentially exacerbating existing health disparities. The US regulatory framework relies on equivalence data to establish that newly introduced medical devices are safe and effective as compared to existing designs. However, there have been well-documented cases of approved implants causing significant harm to patients. Although several studies have demonstrated the equivalence of quality between certain generic and brand name orthopedic implants, concerns regarding small put potentially harmful differences in manufacturing practices and the potential for disparate use of generic implants in economically disadvantaged patients raise ethical questions [9,10]. If generic orthopedic implants were found to have even a minor measurable negative impact on surgical outcomes, this would be a profound violation of the principles of nonmaleficence and the “difference principle” of justice, described by Rawls, that declares inequalities are only permitted if the conditions dictated ultimately benefit, not harm, the worst-off [20].

Although tiered care is already a well-documented facet of American healthcare, its precedence does not justify the further perpetuation of existing disparities. In addition, the variety of generic implants may be limited. This limitation could result in the use of a generic implant that is not optimally suited for a particular condition. If generic implant utilization becomes a widespread normative practice and displaces brand name implants from industry vendors, patient choice could be undercut indirectly by impeding the development of a broader array of implants.

Ethical, regulatory, and policy recommendations

The current trends in healthcare expenditures and the proportion of variable high costs in orthopedic surgery attributable to implant devices suggest that the current orthopedic device marketing and regulation systems do not uphold the principle of justice. Generic implants may address some of the ethical shortcomings of physician-vendor relationships. However, given that generic implants must be manufactured, either by the same companies which produce the branded implants or by other stakeholders, there is still potential for conflict of interest. As purchasing and implant decision power shifts from individual surgeons to institutions, conflicts of interest for physician-vendor relationships could easily be replaced by hospital-vendor relationships for generic implants. This warrants careful ethical and financial analysis of shifting alliances among hospitals, vendors, and surgeons to ensure the well-being of the patient. Establishing ethical implant committees to oversee adherence to standards of professionalism will be critical to ensure net value.

Currently, the medical device approval regulatory framework in the United States is based in the Center for Devices and Radiological Health in the Food and Drug Administration (FDA). The approval of a given implant in the United States requires proof of the device’s safety and efficacy with most orthopedic implants classified as “Class II” or “Class III” devices subject to generic regulation as well as 510(k) premarket notification or approval. A comparative narrative by Maak and Wylie indicates that US FDA approval is more stringent than that in Europe. High-profile cases of implant recalls have placed political pressure on the device regulation industry worldwide to create stricter guidelines. The US FDA approval through the 510(k) pathway and postmarket approval (PMA) pathway was 31 months and 54 months respectively, whereas in the European Union similar device approval through analogous

pathways took 7 months and 11 months, respectively [28]. This cost burden in the United States to innovate and bring devices to market has been used as justification by vendors for the high prices of medical devices. By undercutting prices of proprietary competitors, generic implant utilization could intensify this financial pressure on industry vendors, or even remove the adequate incentive to bring a new device to market.

Policy regulating the implementation of generic implants will need to account for not only the ethical considerations described above, but also the potential loopholes in the existing regulatory framework to satisfy the principle of nonmaleficence. Samuel et al summarize the less rigorous and often-criticized process of orthopedic implant approval through the 510(k) pathway in which expedited approval can be obtained. They further describe that implant devices that retrospectively were required to undergo the PMA process were often modified many times through PMA supplement pathway without clinical data to support the safety of design changes. A relevant finding of their study was that most FDA recalls of PMA devices were not secondary to design flaw but instead a result of issues with processing, packaging, or labeling [29]. These findings support the further expansion of efforts to build national and international orthopedic device registries—with special attention given to the monitoring of generic implants. The responsibility for reporting defective implants, generic or otherwise, is also incumbent upon surgeons to ensure appropriate monitoring and implant evaluation. Adoption of generic implants will require rigorous regulation of supply chain practices to ensure their integrity.

Conclusions

America's rising healthcare costs represent an unsustainable burden on the US economy and are rooted in a myriad of systematic factors. Physicians, including orthopedic surgeons, have a moral obligation to contribute to efforts to contain costs while maintaining the quality of care where they can. The ethical and economic implications of utilizing generic orthopedic implants reviewed in this article suggest that the use of generic implants could be ethically viable and favorable for patients, physicians, and the US healthcare system if cost savings are systematically siphoned to benefit these entities. However, widespread utilization must occur with careful monitoring of these implants and with a well-defined regulatory mechanism in place for assessing the quality and legality of these implants. In addition, without adequate price transparency to facilitate negotiation by hospitals and physicians as well as strategies such as gainsharing to incentivize price reduction, the benefits of generic implants will be limited [16]. Such gainsharing agreements should also acknowledge and address the possible introduction of novel conflicts of interest if the hospital or surgeon benefit from the use of generic implants. Although implant costs are significant, surgical episodes of care are comprised of many costs, and generic implant utilization only impacts a defined portion of these expenses. The current body of evidence demonstrating the economic favorability of generic implants compared to brand name implants is promising, but too small to make definitive recommendations for large-scale changes. As the safety of generic implants is better established with equivalence studies, policies incentivizing surgeons to utilize generic implants appropriately could be included in alternative payment models such as the MACRA. The MACRA program changes Medicare reimbursement to physicians by tying reimbursement to quality of care measures like patient outcomes, cost efficiency, hospital length of stay, and complications of care. If ethically sound means of implementation are prioritized, generic implant utilization as a cost-reduction strategy warrants consideration as a quality metric for emerging legislation and payment restructuring programs such as MACRA [30].

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