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Ethics, Policy and Orthopaedic Surgery

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Disclosures

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Outline – Part 1

Total Joint Arthroplasty
Implant Pricing

- Unsustainable Financial Burden
- The Implant Industry
- Important Questions
- Historical Perspective
- Methods of Cost Control
- New Companies
- The Rep-Less Model
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- Ethical Justification for Cost Control

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Outline – Part 2

Unintended Ethical Consequences of Value Based Care in Total Joint Arthroplasty

- Modifying Risk Factors
- Driving Down the Cost of Care
- Principles of Medical Ethics
- The Argument for Delaying Intervention
- The Harm in Delay
- Regionalization of Care, Centers of Excellence, and Physician Volume
- OR Efficiency and Utilization
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- Introduction to Gainsharing
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- Ethical Concerns
- Support for Gainsharing
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- Methods of Cost Containment
- Patient Outcomes
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Part 1 – Total Joint Arthroplasty Implant Pricing

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Unsustainable Financial Burden

- The number of total joint arthroplasties (TJAs) in the United States continues to grow.
- Current estimates are that approximately 512,000 hip and 787,000 knee arthroplasties are performed annually.
- Many of these procedures are performed on Medicare recipients (~400,000) and TJAs represent the largest share of Medicare spending among inpatient surgical procedures.
- This has created an unsustainable financial burden for the federal healthcare programs and the entire healthcare system at large.
- The Centers for Medicare & Medicaid Services has developed alternative payment models designed to decrease cost without negatively affecting outcomes.
  - The Bundled Payment for Care Improvement (BPCI)
  - Comprehensive Care for Joint Replacement (CJR)
- The cost of implants is highly variable and represents a substantial financial portion of a TJA episode of care.
- Cost containment measures must focus on decreasing implant costs.
- Furthermore, higher-cost prostheses have unproven clinical benefits.

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The Implant Industry

- The U.S. implant industry is an approximately $20-25 billion business, but almost 75% of the current implants have expiring patents
- Only a handful of large companies control 90% of the orthopaedic marketplace
- Most orthopaedic implants receive Food and Drug Administration clearance through the 510(k) process, which is a regulatory pathway that takes only six to nine months and must demonstrate design equivalence only

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Important Questions

- How does the healthcare system meet the increasing demand for hip and knee replacement surgeries?
- How can we control the cost of providing that amount of care?
- How do we deal with the increasing complexity of TJA technology?
- How do we effectively navigate bundled payment systems?
- How do we address decreasing reimbursement to providers?
- How can surgeons be incentivized to seek greater value in their implant choices?

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Historical Perspective

- The U.S. “fee-for-service” structure of the past 30 years has allowed implant costs to run rampant with price increases at an average of 8% per year.
- Some of the earliest published literature on implant prices include a 1993 JBJS article by Barber and Healy which compared the cost of a THA from 1981 to 1990.
  - Hospital costs had an inflation adjusted increase of only 1.9%
  - However, implant costs had an inflation adjusted increase of 117%
    - A $945 implant in 1981 comprised 11% of the hospital cost
    - A $2,947 implant in 1990 comprised 24% of the hospital cost

Implant System	Cost[2]
Primary THA	$5,800
Primary TKA	$4,877
Revision THA	$11,470
Revision TKA	$16,109

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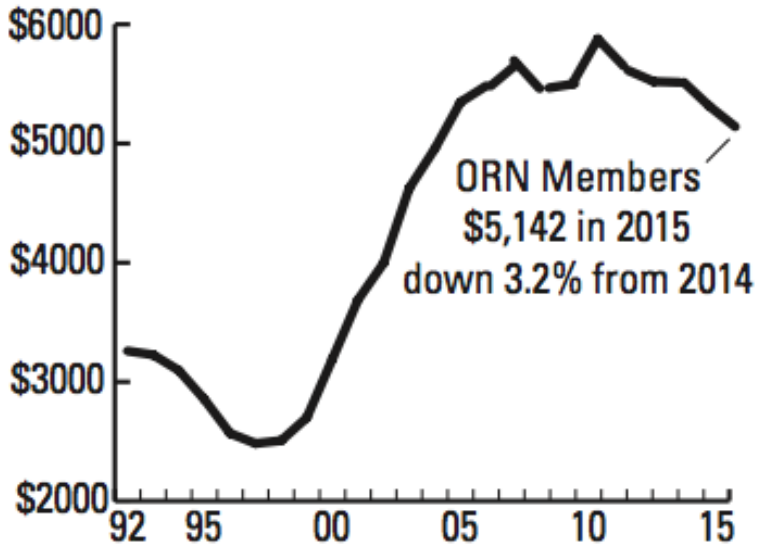
Historical Perspective

- Between 1996 and 2006, the cost of implants rose approximately 130%, although costs have stabilized since 2009, in part due to the cost-containment efforts described below.
- Still, implants can sometimes account for upwards of 60% of the hospital costs for TJA procedures
- There are wide, unexplained cost differences both within and across hospitals that are independent of patient characteristics.
  - Total knee costs ranged from $1,797 to $12,093
  - Total hip costs ranged from $2,392 to $12,651
- Specific technologies can add wide variation to the cost
  - Ceramic heads for TJA increase the system cost by approximately $409 to $1,328 across 5 major manufacturers



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Methods of Cost Control

- Competitive Bidding:
  - Encourages manufacturers to bid against one another and generate the most favorable price for the institution
  - A successful approach since the early 1990s, with reported reductions of 14% in THA implants and 23% in TKA implants

- Price Point Setting:
  - The institution sets a non-negotiable, ceiling price point, and all vendors are welcome to offer products as long as they meet the price
  - A study by Bosco et al. showed a $2 million savings in 1 year with a 26% drop in total knee implants and a 22% drop in total hip implants

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Methods of Cost Control

- Demand Matching:
  - Low-demand patients are matched with less expensive, clinically effective implants and high-demand patients are matched with more expensive implants that may have increased longevity
  - Variable to assign demand include: age, weight, activity level, general health, bone stock.
- Cost Effectiveness Modeling:
  - Creating a decision analysis program to calculate the most cost effective implant for a given patient
  - For patients over 73 years old, alternative bearings in THA implants offer no lifetime financial savings regardless of their incremental cost or a reduction in revision rate.
- Alternative Payment Models:
  - Surgeons and hospitals are incentivized to cut costs and share the financial savings
  - CJR has allowed for surgeon gainsharing up to 50% of the CMS surgeon fee

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New Companies

- When the patent expires on an implant, it is no longer necessary to pay a premium for the product
- Many widely-used implant designs are decades old, and there is minimal differentiation among vendors despite exaggerated comparisons
- Analogous to the revolution that occurred with generic pharmaceuticals, generic implants can bring about billions in cost savings without negatively impacting patient care
- The actual manufacturing cost for TJA implants is significantly less than $1000 per device
- There are multiple companies entering this new value-based marketplace.
- They seek to “de-feature” the devices and decrease the complexity of the system (i.e., fewer trays), thereby making the systems more generic and driving down the cost.
- Traditional companies are starting to enter this marketplace. For example, the S&N Syncera program offers older but successful product lines for a 33% discount

Company	Website
Orthimo	http://www.orthimo.com/
Ortho Direct USA	http://www.orthodirectusa.com/
ImplantPartners (under MicroPort)	http://implantpartners.com/
Syncera (under Smith and Nephew)	http://syncera.com/us
Villoy Implants	http://villoy.com/
Responsive Orthopedics	http://www.responsiveknee.com/
OrthoSolutions	http://www/orthosolutions.com
Intraalign	http://intraalign.com/
Covenant Orthopedics	http://www.covenantortho.com/
NovoSource	http://www.novosource.net/

	Femur	Tibia	Polyethylene
Value System	12 (6R + 6L)	6	6 (2 mm increments)
Premium System	42 (21R + 21L)	18 (9R +9L)	12 (1 mm increments)

The Rep-Less Model

- Implants are traditionally sold by a sales representative
- Sales representatives can account for as much as 30% of an implant company's budget, which often represents their greatest expense
- The sales representative model is designed to push products in the OR. Their training and objective is to sell the surgeon "more for more."
- A growing number of hospitals are excusing sales representatives from the OR and are educating their own employees to assist surgeons
- These sorts of non-commissioned, logistical case specialists are separate from the traditional OR staff and focus only on inventory management and case coverage.
- However, a hospital must have a critical mass of surgical volume to support in-house logistics, and the hospital must be able to incentivize surgeons to participate as aligned, team-players in this value-based approach.
- Removing sales representatives from the operating rooms could improve infection control and mitigate legal risks if there is a lack of informed consent when a patient does not know that a third party representative is in the room.
- Computer technology to analyze, augment and improve areas like hospital work flow and surgeon technique can help replace the role of the representative.

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Relevant Ethical Principles

Autonomy	The obligation to permit patients to make free and informed decisions
Beneficence	The obligation to do good for and act with the intention of helping the patient
Nonmaleficence	The obligation to not inflict harm upon others
Justice	The obligation to fairly distribute resources among those in need and be a steward of finite resources
Utilitarianism	The morally correct action is the one that produces the greatest good for the greatest number

Necessary for Autonomy[1]
Capacity to understand information and communicate a choice
Capacity to reason and deliberate
Capacity to entertain multiple consequences and alternatives

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Pitfalls with Cost Control

- Assigning value
  - Patient characteristics must be assigned a relative positive or negative value in any utilitarian decision-making algorithm
    - For example, a patient with a high BMI is a high risk for poor outcomes at TJA, so a relative negative value is assigned to a high BMI compared to a low BMI
  - Assigning value in this manner may be discriminatory, especially if the variable under consideration is not modifiable in the pre-operative setting.
- Gray areas at the margins
  - Decision-making algorithms may not be applicable at the margins
    - For example, A 55 year-old male with a BMI of 20 may fall into a demand-matched category for a lower demand THA implant. However, this patient may actually mountai bike multiple times a week, thereby placing high demand on the implant
- Assessing quality
  - The true quality of implants cannot be known until decades post-implantation; however, under-valuing all newer and more expensive technologies until they develop long-term results very well might decrease the likelihood of true medical advancement
  - Some aspect of quality and patient outcome are not easily captured with current metrics, such as a new TKA implant design that might feel more “natural” to a patient but with no other discernible improvement over the prior model

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Ethical Justification for Cost Control

- New technology innovations will make it easier to assign value and assess quality
  - E.g., wearable technologies that can help assess a patient's activity level, "big data" analysis of implant longevity from growing registries, etc.
- Surgeons are obligated to practice reflective, evidence-based medicine and improve their specialty area for the overall good of their patients.
- It is impossible for patients to exercise true autonomy in making decisions about implant technology, and surgeons must guide their choices.
- In a setting with little oversight or restriction on implant costs, vendors may charge unrealistic prices and surgeons may chose more expensive implants based on vendor recommendation rather than clinical outcomes.
- In the absence of a clinical benefit that justifies the cost of a more expensive implant, choosing implants without supporting evidence does not maximize the utilitarian stewardship of the health care system
- Maximizing the value equation (quality/cost) through restricted use of unnecessarily expensive implants is ethically justified and economically sensible.

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Part 2 – Unintended Ethical Consequences of Value Based Care in Total Joint Arthroplasty

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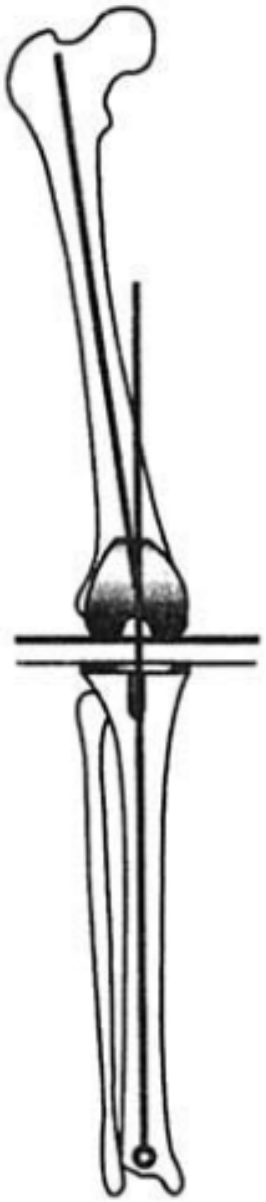
Modifying Risk Factors

- The current environment of limited healthcare resources demands efficient delivery of medical care within a sustainable system
- Several initiatives of the Patient Protection and Affordable Care Act of 2010 require that hospitals simultaneously improve quality and decrease the cost of care, or else face financial penalties
- One strategy to achieve more efficient care is to decrease the number of risk factors for poor outcomes
- There are multiple risk factors for poor outcomes in patients undergoing total joint arthroplasty
  - Some risk factors are related to the surgeon and hospital
    - Implant positioning, operative time, patient volume, peri-operative care team
  - Other risks are related to the patient
    - Obesity, diabetes control, nutritional depletion, tobacco use, cardiovascular disease, psychiatric illness, venous thromboembolic disease, drug and alcohol dependence
- For an elective surgery such as total joint arthroplasty, there is a strong justification to modify these risk factors preoperatively, although doing so raises significant ethical questions.
  - It is morally justifiable for both patients and surgeons take a more active role in decreasing risk



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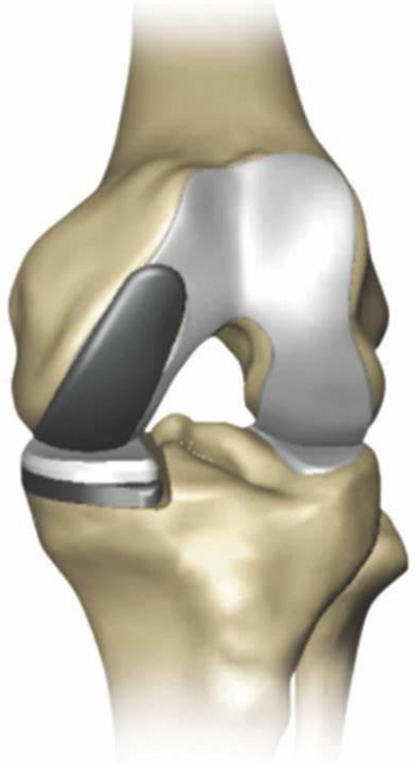
Driving Down the Cost of Care

- Current estimates are that approximately 512,000 hip and 787,000 knee arthroplasties are performed annually.
- Many of these procedures are performed on Medicare recipients (approximately 400,000) and total joint arthroplasty represent the largest share of Medicare spending among inpatient surgical procedures.
- The Centers for Medicare & Medicaid Services has developed alternative payment models designed to decrease cost without negatively affecting outcomes.
  - The Bundled Payment for Care Improvement
  - Comprehensive Care for Joint Replacement
- The cost of implants is highly variable and represents a substantial financial portion of a total joint arthroplasty episode of care, and higher-cost prostheses have unproven clinical benefits.
- One option to control costs engages surgeons in gainsharing to encourage decision-making that results in less expensive care
  - Only when implemented in a thoughtful, regulated manner might gainsharing represent an ethically justified model
- Another option to help defray costs might be to allow patients to contribute to the cost of their implants
  - Pro: potential to enhance autonomy and transparency, respects shared decision-making, strengthen financial viability of the health care system
  - Con: lack of evidence-based data, absence of independent review process, increases healthcare disparities



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Principles of Medical Ethics

Autonomy	The obligation to permit patients to make free and informed decisions
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Justice	The obligation to fairly distribute resources among those in need and be a steward of finite resources
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$$Value = \frac{Quality}{Cost}$$

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The Argument for Delaying Surgery

- Obligation of non-maleficence may demand we decrease patient risk in order to avoid harming patients (infection, revision, etc.)
  - Some patients who suffer major complications (resistant infection resulting in amputation, for example) are likely better off never having had surgery
- It is a potential moral obligation to do so. Failing to address easily modifiable risk factors places patients at potentially unnecessary risk
- In an era of cost containment, obligation of justice demands that physicians decrease the cost of care through decreasing modifiable patient risk factors.

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The Harm in Delay

- By demanding modification prior to elective joint replacement, patient autonomy is decreased as physicians may limit access of some patients before an attempt is made to decrease risk
- This loss of autonomy is acceptable in order to limit potential harms to patients and improve overall outcomes
- But will this decrease patient access to surgery? No.
  - 1) This only refers to modifiable risk
  - 2) Surgery will merely be delayed, hopefully not denied, in an attempt at modifiable risk reduction
- Ultimately, a shared-decision making model is more appropriate both for patient welfare and cost-effectiveness
  - the patient and surgeon participate in elective treatment decisions together, only after weighing risk and what might be done to reduce it

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Regionalization of Care, Centers of Excellence, and Physician Volume

- Ethical Considerations – Pro
  - Beneficence and non-maleficence demands that physicians avoid harming patients
  - Referral to high volume physicians and centers may result in improved patient outcomes and avoidance of patient harms
  - Stewardship requires the efficient use of resources which can best be obtained by minimizing poor outcomes and maximizing success rates and patient satisfaction
- Ethical Considerations – Con
  - Limited access for socioeconomic disadvantaged patients who cannot travel to distant quality centers
  - Effect of out-migration of specialty physicians on communities could be detrimental to local economies as well as on hospital ability to handle emergencies
  - Decreased patient autonomy in choosing their own center and physician

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OR Efficiency and Utilization

- The majority of the cost of total joint replacement occurs within the operating room

- Can we make ORs more efficient?
  - Increased number of cases/day = increased revenues
  - Encouraging surgeons to operate faster
  - Will this help of harm patients? Is there a “sweet-spot” for case duration and patient outcomes
  - Need to balance speed with patient safety

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Implant Restriction

- The economics of TJA requires physician-hospital alignment in lowering cost

- Should we restrict implant use and/or demand lower prices?
  - Reference pricing to decrease cost variability
  - Using older, cheaper, proven implants
  - Demand-matching implants and patients

- Economically it makes sense, but is it fair?
  - Decreased patient and physician autonomy
  - Potential decrease in quality (even if increase in value)

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Introduction to Gainsharing

- Defined as a financial partnership between hospitals and physicians in which both parties work to decrease costs, and the hospitals then share a portion of the savings with the physicians
- Detailed safeguards are necessary to avoid violating three relevant laws…
  - Anti-Kickback Statute: cannot receive or give rewards for patient referrals or business
  - Physician Self-Referral Law (Stark Law): cannot benefit directly from patient self-referral
  - Civil Monetary Penalties Law: the Office of the Inspector General may penalize for misconduct

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Gainsharing in Orthopaedic Surgery

- The Comprehensive Care for Joint Replacement bundle included voluntary gainsharing between hospitals and collaborators
- Comprehensive regulations were put in place to avoid illegal activity
- Surgeons are limited to 50% of the CMS surgeon fee

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Ethical Concerns

- Surgeons and Hospitals
  - Every surgeon has an obligation to obey the ethical principles of beneficence and nonmaleficence, but subtle biases may arise when financial compensation is at stake
  - Surgeons may be uncomfortable with the preferred implant systems negotiated by hospitals
  - There are unforeseen legal liabilities if the Department of Justice finds that gainsharing programs qualify as kickbacks or self-referrals
- Patients and Society
  - Patients may have reduced access to perceived improved technologies because of their cost which may exchange short-term savings for decreased implant survival and patient function
  - Patient advocacy may no longer be at the forefront of a physicians decision-making
  - Patient autonomy is not respected if patient's do not approve of gainsharing arrangements
  - "High-risk" patients may face discrimination and access denial because they represent a financial liability
- Industry
  - Cost control efforts may stifle innovation and encourage restrictive markets or monopolies

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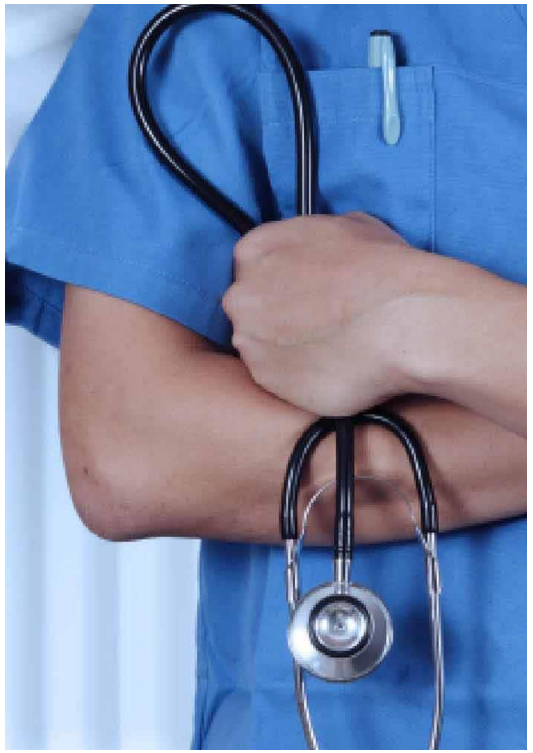
Support for Gainsharing

- Surgeons and Hospitals
  - Surgeons are best equipped the advocate for their patients when making financial decisions
  - Gainsharing offers new revenue streams for surgeon practices
  - Hospitals may utilize gainsharing both to retain top surgical talent and mitigate financial risks
- Patients and Society
  - Gainsharing promotes co-management and cooperation between hospital and surgeons which ostensibly produces a more efficient, higher quality health care system
  - Transparency about gainsharing programs will engage patients in a new manner
  - Any efforts to control healthcare costs, gainsharing included, respect the principle of social justice because those efforts improve the long-term financial viability of the system
- Industry
  - High-quality and low-cost competitors may alter the industry landscape and promote innovation



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Implant Costs

- Between 1996 and 2006, costs rose about 130%, however, the process has stabilized since 2009.
- There are wide, unexplained differences in cost within and across hospitals that are independent of patient characteristics.

Implant System	Cost[1]
Primary THA	$5,800
Primary TKA	$4,877
Revision THA	$11,470
Revision TKA	$16,109

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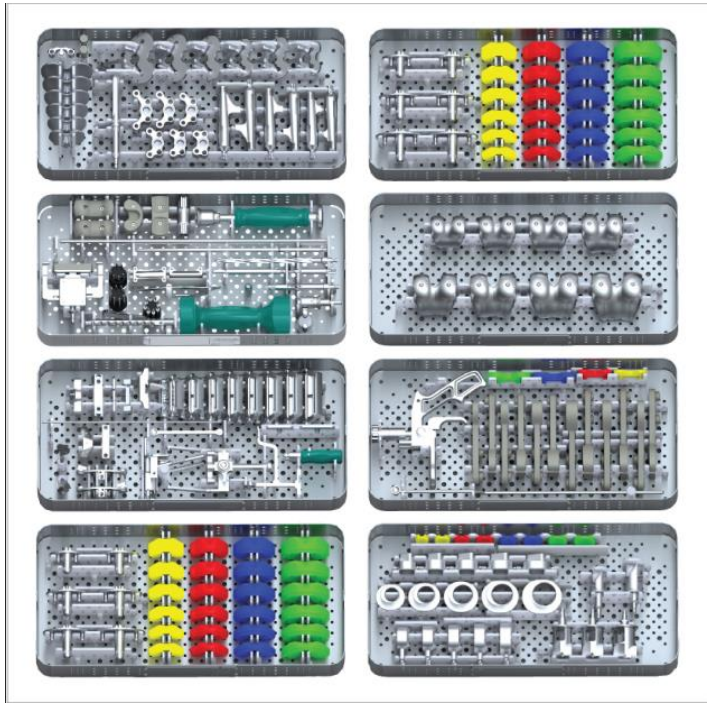
Methods of Cost Containment

- Competitive Bidding: Manufacturers bid against one another and the low-cost contract wins
- Price Point Setting: The institution sets a ceiling price point, and all vendors are welcome to match
- Demand Matching: Low-demand patients are matched with less expensive, clinically effective implants and high-demand patients are matched with more expensive implants that may have increased longevity
- Cost Effectiveness Modeling: Creating a decision analysis program to calculate the most cost effective implant for a given patient
- Alternative Payment Models: Surgeons and hospitals are incentivized to cut costs and keep savings



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Patient Opinions

- Multiple studies have shown that patients are willing to pay out of pocket for joint implants
- For example, two surveys found patients willing to pay median out of pocket costs of $2,000 (range $1000-5000) and $2,240 (range $3-$20,000)

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In Favor of Cost-Sharing

- Empowering patients to be involved in the choice of their implants respects patient autonomy
- Improved transparency about implant selection can enhance informed decision-making
- Shifting healthcare costs to individual patients can improve the long-term viability of the social system
- A financially stable and sustainable implant market might enhance implant innovation
- There is a general social consensus in the U.S. that wealthy individuals should be able to spend their money as they see fit, so long as they are not harming themselves or others.

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Against Cost-Sharing

- Without adequate information about implant technology and focused patient education, true autonomy is not possible
- Surgeon-industry relationships may cloud a surgeon's counsel
- Perverse incentives may enter the system…
  - Industry may introduce new products with unproven benefit
  - Hospitals and surgeons may develop a bias towards self-paying patients
- Already pre-existing socioeconomic healthcare disparities could be worsened
- The true quality of a total joint arthroplasty implant is not known until many years after implantation, and allowing patients to make decisions about implant technology based on assumption is ethically dubious
- A new system must be developed to evaluate implant technologies that is more comprehensive than the current Food and Drug Administration 510(k) process

Necessary for Autonomy[5]
Capacity to understand information and communicate a choice
Capacity to reason and deliberate
Capacity to entertain multiple consequences and alternatives

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References – Part 1

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The End

- Thank You
- Questions?

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