Published in final edited form as:
Arthritis Care Res (Hoboken). 2013 January ; 65(1): 148–151. doi:10.1002/acr.21826.

Preceding the Procedure: Medical Devices and Shared Decision-Making

Julian J. Prokopetz, BA, **Jeffrey N. Katz, MD, MSc**, **Elena Losina, PhD**, **Thomas S. Thornhill, MD**, **John Wright, MD**, and **Lisa Soleymani Lehmann, MD, PhD**
Department of Orthopedic Surgery (JJP, JNK, EL, TST, JW), Division of Rheumatology, Immunology and Allergy (JNK, EL), Center for Bioethics (LSL), Brigham and Women's Hospital; Department of Epidemiology, Harvard School of Public Health (JNK); Department of Biostatistics, Boston University School of Public Health (EL), Boston, MA

Carl Thomas is a man in his early fifties with osteoarthritis of the hip. He and his orthopedic surgeon, Dr. Jones, discuss various treatment options and ultimately decide on total hip replacement (THR). Dr. Jones reviews the procedure with him and confirms that he understands his options. Then Mr. Thomas signs the surgical consent form.

This discussion appears to include all the elements of informed consent, but several ethical questions linger beneath the surface. Dr. Jones discussed the risks and benefits of total hip replacement in some detail to help Mr. Thomas decide whether or not to have surgery, but should Mr. Thomas also have participated in the decision about the specific implant to be used?

This article teases out the ethical issues underlying the choice of a medical device for surgical procedures, using the example of total joint arthroplasty to illustrate the interactions between surgeons and their patients. We highlight shortcomings in the current regulatory process that result in a thin evidence base on which to anchor these technical decisions, and we note the potential for decisions to be influenced by the surgeon's personal beliefs and possible conflicts of interest. We suggest that the informed consent process could be enriched with a greater focus on shared decision-making. This would include discussing the choice of implant and other technical decisions that may affect the outcome of the procedure, in addition to disclosing any relevant financial relationships. We note the challenge of providing patients with easily digestible information that helps them make decisions consistent with their own values. The Table highlights the most salient aspects of the conversations that we suggest occur between surgeons and their patients. We focus our discussion around the example of total joint replacement, but these issues are generalizable to decisions about non-orthopedic devices such as cardiac pacemakers, stents, and implantable defibrillators, as well as innovative, technically complex, and potentially risky non-surgical therapies like biologic agents for rheumatic conditions.

Background

Elective total hip and knee replacements are increasingly common procedures that are performed on nearly one million patients every year in the United States.(1) Medical device companies regularly introduce new implants designed to last longer or function better. Under the Food and Drug Administration's Section 510(k) expedited review process, these devices can be approved for sale without formal testing in clinical trials as long as they

Correspondance: Jeffrey N. Katz, MD, MSc, Orthopedic and Arthritis Center for Outcomes Research, Brigham and Women's Hospital, One Brigham Circle, Suite 4016, Boston, MA 02120, jnkatz@partners.org, Phone: 617-732-5338, Fax: 617-525-7900.

confer low or moderate risk to patients and are structurally similar to a previously approved device.(2) However, the previously approved device could *also* have been approved under 510(k), leading to daisy chains of approved devices going back for decades, most of which have not undergone rigorous premarket assessment in human subjects.

Manufacturers typically demonstrate the advantages of their latest implants in laboratory simulation studies.(2) The hope is that these prostheses will confer similar advantages in real patients, but long-term durability and complication rates cannot be confirmed empirically in humans until the implant has been in use for several years. Prompted by these and other concerns, the Institute of Medicine recently reviewed the 510(k) system and concluded that the expedited process is flawed and does not adequately protect patient safety.(2)

Studies have shown that some surgeons tend to be early adopters of technology, often incorporating their preferred vendor's newest models into their surgical repertoire when they become available.(3, 4) Surgeons report that they typically face few institutional constraints on their choice of implants,(3) so many are able to decide for themselves when they wish to begin using newer models. This situation is evolving, however, as hospitals and health systems increasingly play a role in controlling global costs of procedures.

Newer products may well demonstrate improved longevity, but they occasionally have unforeseen risks and complications, as evidenced by the current set of investigations over the early failures of metal-on-metal hip replacements.(5, 6) The US orthopedic implant market is particularly vulnerable to these unforeseen problems because there is no comprehensive national arthroplasty registry or formal post-market reporting system to track them.(7) Indeed, Mr. Thomas and Dr. Jones have limited scientific evidence on which to base their implant decision, and may rely on Dr. Jones's personal beliefs and experience.

Conflicts of Interest

The choice of implant is complicated further by the possibility for conflicts of interest stemming from the consulting fees that some orthopedists receive from device manufacturers. In 2007, the five largest manufacturers made payments to approximately 4% of the 25,000 registered orthopedic surgeons in the United States.(8) These payments typically involve surgeons in high-volume practices(3) and academic settings.(8) Orthopedists who receive industry support express, on average, a greater sense of shared goals and priorities with their vendors and sales representatives than surgeons who don't.(3) These surgeons may well use and support the devices of a particular manufacturer because they believe them to be of superior quality, but the risk of disrupting their financial ties with the company nonetheless constitutes a conflict of interest when deciding which products to recommend to their patients.

A 2007 Department of Justice investigation into the financial arrangements between implant manufacturers and orthopedists resulted in stringent requirements for public disclosure of all such payments.(9) Similar disclosure requirements were included in the Physician Payment Sunshine Act, which went into effect earlier this year as part of the federal health care reform legislation.(10) Some surgeons choose to disclose their financial relationships with device manufactures directly to their patients, but such disclosures are not mandated by law.

Shared Decision-Making

Before we outline our suggested approach for surgeons and patients to discuss these issues, it is important to clarify the context in which these discussions occur. Medical devices and the surgical procedures used to implant them often allow for a broad array of choices and specifications. In the context of THR, this includes decisions such as a total hip replacement

vs. a hip resurfacing device (a smaller implant that preserves more bone stock), variations in implant materials and bearing surfaces (e.g. metal, ceramic, polyethylene), implant fixation method (surgical cement vs. relying on bone ingrowth), and surgical exposure (anterior, lateral, or posterolateral incision).

The total set of possible permutations with regard to device features and surgical techniques is vast, so surgeons typically work with a small number of implants at any given time in order to maximize their proficiency with the technology.(3) In the absence of comparative data, this personal experience with a particular brand may be a powerful determinant of surgeon preference. New technologies bring steep learning curves, so surgeon familiarity with a given implant may be as important as the technical features of the implant itself in predicting patient outcomes.(11–13) Thus, surgeons don't select an implant for each patient from the entire range of options available on the market; rather, they decide which of the few implants they currently offer are appropriate options.

In some clinical circumstances, surgeons may feel there is a single obvious choice of device. In patients over the age of 75, for example, the risk of mortality in the years following THR is up to ten times higher than the risk of prosthesis failure.(14) Thus, older patients are unlikely to realize additional benefits from a newer implant that promises greater longevity, but they face greater risks than younger patients from surgical complications should revision be necessary.(15) This suggests that an older, more familiar device with known complication rates may be the most logical choice. In this case, it's not so much a question of comparing various brands and designs, but rather of explaining to the patient why the surgeon is recommending a particular implant, highlighting the clinical evidence (or lack thereof), and disclosing any financial ties to the device manufacturer. If a patient is unsatisfied with this recommendation and strongly prefers an implant the surgeon is not comfortable using, he or she may seek out another provider who offers a different set of implants.

In other situations, surgeons may feel there is a meaningful choice to be made between two or more devices in their repertoire that they consider to be appropriate for their patient's demographic and clinical characteristics. A younger, more active patient like Mr. Thomas, for example, has a higher likelihood of requiring a revision at some point, so Dr. Jones may wish to offer him the choice between a newer, potentially longer-lasting implant (e.g. a hip resurfacing device or a prosthetic joint with alternative bearing surfaces) and an established device with better-known long-term outcomes. Patients may differ in their attitude toward unknown risks and new technologies, so we suggest that in addition to providing information on empirical testing and financial relationships, Dr. Jones ought to solicit his patient's input so that Mr. Thomas's values and preferences play a role in the final decision.

This conversation is not meant to supplant the traditional explanation of risks, benefits, and alternatives; rather, we suggest that incorporating a shared decision-making framework would produce a more robust and preference-sensitive informed consent discussion. Traditionally, there have been three approaches to assessing disclosure in informed consent.(16) The "professional" standard is based on what other physicians would disclose in a similar situation; it has been criticized as being too physician-centered, reflecting only what the physician deems important for the patient to know. Also troubling is the implicit assumption that if many physicians do the same thing, it must therefore be correct. The "reasonable person" standard is based on what a reasonable person would want to know; this model approaches the issue of informed consent from the patient perspective, but leaves us to resolve the ambiguity inherent in defining a "reasonable" person.

To mitigate the tension between these two views, some have proposed a “subjective” standard, based on the physician’s assessment of each individual patient’s needs. This model calls on physicians to build on the “reasonable person” standard and personalize their informed consent discussions, presenting any information they feel is pertinent to the particular patient sitting in front of them. This approach dovetails nicely with the concept of shared decision-making, in which the physician solicits the patient’s values and preferences to help guide the discussion of clinical options in a personally meaningful way. This creates a patient-centered process with an emphasis on ensuring a good fit between each patient’s characteristics and values and the treatment decision.

Regardless of the approach surgeons take in determining what information to include in the informed consent discussion, some may view the process as a one-way transfer of information, from surgeon to patient. Enhancing that conversation with the kind of patient participation we suggest in this paper presents some intricate challenges. Notably, details of implant design or biomaterials may be viewed by some as too technically complex for most patients to grasp and discuss in a meaningful way. In a 1999 study, for example, 93% of patients said it should be up to the surgeon to select the prosthesis (as opposed to 6% who thought the surgeon and patient should decide together).(13) A typical patient may not understand or desire a detailed description of the design features of a particular implant, and may wish to leave the decision entirely in the surgeon’s hands.

We propose that these preferences be respected after the tradeoffs of alternative devices are clearly explained, but that patients should be offered the opportunity to engage with their surgeon’s recommendations and share their preferences and concerns, including their willingness to accept short- and long-term risk. The conversation can be framed in layman’s terms to help patients grasp the key features that distinguish the implants the surgeon is offering, balancing known risks against potential but unproven benefits. This is the essence of shared decision-making: providing patients with information that permits them to make a preference-consonant decision.(17, 18) Patients may still wish to defer to their surgeon for the final decision, but they should be presented with options that have meaningful implications for their outcomes. If they wish to share their thoughts, those values should guide the discussion.

We recognize that not all patients possess the desire or capacity to make decisions involving nuanced technical details, and that incapacity is often not recognized by physicians. These observations introduce another layer of complexity to the process, especially among patients with cognitive limitations. If such patients have a health care agent making decisions on their behalf, then we suggest that the surgeon engage the agent on the issues we have mentioned. Health care agents are meant to be the patient’s voice, to make the decisions they think the patient would have made, and they may have thoughts on the patient’s values and feelings about risk. For impaired patients who don’t have a health care agent, the “subjective” disclosure standard provides a helpful framework with its emphasis on an informed consent conversation tailored to the individual patient’s needs: even competent patients may prefer that their surgeon decide what’s best for them after discussing the various implant options, but patients with cognitive limitations and no competent proxy may perhaps be best served if their surgeon simply recommends the implant he or she feels is most appropriate.

Looking forward, the issues raised here suggest several areas for further work. We do not presently know the extent to which surgeons and patients discuss the many facets of implant choice, so additional research is needed on how they currently handle these conversations. The findings of such research could inform strategies for incorporating issues of financial disclosure and implant alternatives. Second, we suggest that professionals with expertise in

shared decision-making work with surgeons to develop effective tools to facilitate these conversations.(20, 21) Similarly complex discussions, such as deciding between total joint replacement and non-operative therapy for advanced arthritis, have been enhanced with the use of formal decision aids that provide accessible, understandable information on options, risks, and benefits.(18) We also need to deepen our understanding of how to optimize the process among patients with limited decision-making capacity.(19) To increase awareness and consideration of these issues, they can perhaps be integrated more formally into medical school, post-graduate surgical training, or continuing medical education initiatives. Finally, the issues raised in this article underscore the need for central adverse event reporting systems for the wide range of medical devices used in humans so that we may accurately assess potential problems arising in new models.(7, 22, 23) We note that the concerns we have highlighted in the context of total joint replacement are pertinent to the growing range of implantable devices used across medical and surgical fields, including cardiac valves, stents, defibrillators and pacemakers, gastrointestinal stents, implantable analgesic delivery systems, and many others.

Mr. Thomas will have a prosthetic hip for the rest of his life. The ambiguities and unknowns of the available devices and approaches suggest that the decision is not necessarily one of choosing the *best* implant, but rather of opening a dialogue with his surgeon and deciding on an implant with a balance of advantages and drawbacks consistent with Mr. Thomas's preferences. If Dr. Jones explains what the available options represent in terms of the new and the familiar, discloses any financial ties to the manufacturers of the devices being considered, and engages Mr. Thomas in a values-based discussion of potential risks and benefits, then together, they may arrive at a decision that mirrors Mr. Thomas's own conception of his best interests more closely than if Dr. Jones had simply made the choice on his own.

Acknowledgments

Supported by NIH P60 AR 47782 (JNK, EL), NIH K24 AR 057827 (EL), NIH 1UL1RR025758-01 from the Harvard Catalyst (LSL), and the Safra Center for Ethics, Harvard University (LSL). Two authors receive consulting fees (JW) or royalties (TST) from orthopedic implant manufacturers. Their experience with orthopedic surgery and the related industry enriched the piece, and the companies in question played no role in drafting, editing, or final approval.

References

1. Agency for Healthcare Research and Quality. HCUP Nationwide Inpatient Sample. United States Department of Health & Human Services. 2009.
2. Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years. Washington, DC: Institute of Medicine, The National Academies Press; 2011.
3. Burns LR, Housman MG, Booth RE Jr, Koenig A. Implant vendors and hospitals: competing influences over product choice by orthopedic surgeons. Health Care Manage Rev. 2009; 34(1):2–18. [PubMed: 19104260]
4. Wilson CB. Adoption of new surgical technology. BMJ. 2006; 332(7533):112–114. [PubMed: 16410591]
5. Medicines and Healthcare products Regulatory Agency. Medical Device Alert: All metal-on-metal (MoM) hip replacements. London, UK: Department of Health; 2010 Apr 22. 2010. Report No.: MDA/2010/033.
6. Langton DJ, Jameson SS, Joyce TJ, Hallab NJ, Natu S, Nargol AV. Early failure of metal-on-metal bearings in hip resurfacing and large-diameter total hip replacement: A consequence of excess wear. J Bone Joint Surg Br. 2010; 92(1):38–46. [PubMed: 20044676]
7. Maloney WJ. National Joint Replacement Registries: has the time come? J Bone Joint Surg Am. 2001; 83-A(10):1582–1585. [PubMed: 11679613]

8. Hockenberry JM, Weigel P, Auerbach A, Cram P. Financial payments by orthopedic device makers to orthopedic surgeons. Arch Intern Med. 2011; 171(19):1759–1765. [PubMed: 22025434]
9. Healy WL, Peterson RN. Department of Justice investigation of orthopaedic industry. J Bone Joint Surg Am. 2009; 91(7):1791–1805. [PubMed: 19571103]
10. Fact Sheet: Physician Payments Sunshine provisions in Health Care Reform. Boston, MA: Pew Prescription Project; 2010 Mar 23. 2010
11. Kempton LB, Ankerson E, Wiater JM. A Complication-based Learning Curve From 200 Reverse Shoulder Arthroplasties. Clin Orthop Relat Res. 2011; 469(9):2496–2504. [PubMed: 21328021]
12. Sandhu JS, Maschino AC, Vickers AJ. The Surgical Learning Curve for Artificial Urinary Sphincter Procedures Compared to Typical Surgeon Experience. Eur Urol. 2011
13. Sharkey PF, Sethuraman V, Hozack WJ, Rothman RH, Stiehl JB. Factors influencing choice of implants in total hip arthroplasty and total knee arthroplasty: perspectives of surgeons and patients. J Arthroplasty. 1999; 14(3):281–287. [PubMed: 10220180]
14. Katz JN, Wright EA, Wright J, Malchau H, Mahomed NN, Stedman M, et al. Twelve-year risk of revision following primary total hip replacement in the US Medicare population. Journal of Bone and Joint Surgery. 2011 (provisionally accepted for publication).
15. Mahomed NN, Barrett JA, Katz JN, Phillips CB, Losina E, Lew RA, et al. Rates and outcomes of primary and revision total hip replacement in the United States medicare population. J Bone Joint Surg Am. 2003; 85-A(1):27–32. [PubMed: 12533568]
16. Childers R, Lipsett PA, Pawlik TM. Informed consent and the surgeon. J Am Coll Surg. 2009; 208(4):627–634. [PubMed: 19476800]
17. Emanuel EJ, Emanuel LL. Four models of the physician-patient relationship. JAMA. 1992; 267(16):2221–2226. [PubMed: 1556799]
18. O'Connor AM, Llewellyn-Thomas HA, Flood AB. Modifying unwarranted variations in health care: shared decision making using patient decision aids. Health Aff (Millwood). 2004 Suppl Variation:VAR63-72.
19. Sessums LL, Zembrzuska H, Jackson JL. Does this patient have medical decision-making capacity? JAMA. 2011; 306(4):420–427. [PubMed: 21791691]
20. Fowler FJ Jr, Levin CA, Sepucha KR. Informing and involving patients to improve the quality of medical decisions. Health Aff (Millwood). 2011; 30(4):699–706. [PubMed: 21471491]
21. Gramlich EP, Waitzfelder BE. Interactive video assists in clinical decision making. Methods Inf Med. 1998; 37(2):201–205. [PubMed: 9656665]
22. von Knoch F, Malchau H. Why do we need a national joint replacement registry in the United States? Am J Orthop (Belle Mead NJ). 2009; 38(10):500–503. [PubMed: 20011738]
23. Vidi VD, Matheny ME, Donnelly S, Resnic FS. An evaluation of a distributed medical device safety surveillance system: the DELTA network study. Contemp Clin Trials. 2011; 32(3):309–317. [PubMed: 21356331]

Table

Topics to Include in Discussions of Medical Devices
• Risks and benefits of the procedure(s) and implant(s) that the surgeon considers to be appropriate for the patient • Level of scientific evidence in support of the procedure(s) and implant(s) • Disclosure of relevant financial relationships • Confirmation of patient understanding • Elicitation of patient preferences, concerns, and expectations