

## Virtual Mentor

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### CLINICAL CASE

#### **New Devices and Truly Informed Consent**

Commentary by Charles Rosen, MD

Amy, a medical student, joins her attending physician to obtain informed consent from Mrs. Jones for spinal surgery. The surgeon explains the expected recovery and rehabilitation to Mrs. Jones, who is 70 years old, along with the probable consequences of forgoing surgery. She enthusiastically agrees to the surgery. Her husband walks regularly and she is eager to accompany him in his routine. The attending surgeon schedules Mrs. Jones to have dynamic stabilization system B, a newer class of pedicle screw, implanted into her spine.

Amy is worried that Mrs. Jones is not aware of her option to have a more tried-and-true system implanted instead of System B. System B is FDA-approved, but it is one of many dynamic stabilization devices for spinal fusion whose manufacturers the FDA is requiring to conduct postmarket surveillance of device fusion and adverse events, including failure rates. Recently, Amy read about several national record-keeping systems that track outcomes for other medical device implants. The Swedish hip register, for example, tracks hip implants for 10 years post-surgery. A physician expert in this register estimated that “the risk in the United States that a patient will need a replacement procedure because of a flawed product or technique can be double the risk of countries with databases...and doctors in Sweden are much less likely than American doctors to embrace new devices until registry data show they work.” Is the surgeon ethically obligated to tell Mrs. Jones about the FDA surveillance and to explain the different stabilization systems to her?

### **Commentary**

Yes, he is. In order to give truly informed consent, Mrs. Jones has the right to be informed, in lay terms understandable to her, about two crucial matters: the surgeon’s reasons for preferring one device over the possible alternatives and the device’s status and performance.

If a physician prefers one treatment over another, as in Mrs. Jones’ case, the patient has a right to know why. Different procedures have different risks; some procedures are more or less familiar to or difficult for individual surgeons; and some surgeons want opportunities to try out new procedures. This is part of the basis upon which treatments are advised and, as such, the patient should know. For instance, if a surgeon does not recommend the best procedure for the patient because he or she does not perform it well, then the surgeon should make that known and maybe even refer the patient to another surgeon. As importantly, the surgeon is obligated to tell Mrs. Jones if he or she has received money from the company that manufactures the

device for any type of work, and how much. The quality of patient care must not be subordinated to other concerns.

In addition to disclosing financial involvement with the device manufacturer, the surgeon is definitely obligated to tell Mrs. Jones about alternatives, as well as the fact that the device has only been in use a short time and therefore has not stood the test of time as more established procedures have. Mrs. Jones should be clearly told that postmarketing surveillance is still being conducted on the device in question, and that questions regarding its efficacy are arising from financially independent sources. It is the responsibility of the surgeon to be knowledgeable about these issues in order to advise implantation of the device.

The surgeon must also remain aware of potential bias in device research and tracking. U.S. surgeons are often earlier adopters of new technology that may be problematic because they believe that what they read is true independent validation. The dearth of disclosure among high-profile, highly paid consultant physicians leads to a false impression that device research is unbiased. The objectivity of the reported data is also being questioned because of potential bias among researchers due to financial relationships with manufacturers [1, 2]. Also, surgeons in the U.S. don't have the government registries that other countries' surgeons have to quickly and objectively see outcomes and complications. Because such registries put inferior products at a disadvantage, manufacturers, and many medical society officers who are highly paid consultants for industry discourage them.

To address such issues, I founded and am president of the Association for Medical Ethics (AME), which has over 200 physician members from 11 different countries, and which is entirely self-funded. Ethical Rules of Disclosure were developed by AME after a joint symposium with the University of California, Irvine, School of Medicine [3]. These address such issues as specificity in disclosures: is reading a disclosure that says an author is a consultant for Company X the same as reading a disclosure that says the author received a million dollars last year from the manufacturer of the device being researched? No, it is not. If readers and patients knew the amount of money involved in such relationships, they would be better informed about the possibility of bias, intentional or unintentional, and might be more reticent to use devices. Patients comprehend these issues readily regardless of educational level.

Furthermore, apart from assessing potential bias, physicians should know if the quality of data is strong—Levels I and II—or weaker—Levels III, IV, V—when evaluating whether new procedures or drugs should be used. It is the objectivity of medical research that should be of paramount concern, more so than the famous author or institution from which the data comes.

Another important part of the surgeon's job in obtaining informed consent is speaking to the patient in understandable lay terms. Spouting technical language, though easier for the surgeon, can be alienating as well as be incomprehensible.

There is no reason that analogies and examples to explain procedures cannot be formulated. If being creative in explanations is required to ensure patient understanding, then it should be done. This will strengthen trust between patients and physicians by allowing patients to grasp the nature of the procedures they are having. In order to keep the art of medicine alive, that trust between physicians and patients cannot be abused. Patients like Mrs. Jones deserve no less than complete and understandable information in order to make their decisions.

### References

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2. Zimmer remains committed to spine system despite FDA setback. *Times Union*. November 5, 2009. <http://www.timesuniononline.com/main.asp?Search=1&ArticleID=43691&SectionID=2&SubSectionID=224&S=1>. Accessed January 14, 2010.
3. Association for Medical Ethics. Ethical rules of disclosure. [http://www.ethicaldoctor.org/Ethical\\_Rules\\_of\\_Disclosure.html](http://www.ethicaldoctor.org/Ethical_Rules_of_Disclosure.html). Accessed January 14, 2010.

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