Should physicians be expected to disclose conflicts of interest?

Should physicians who request products be required to disclose any financial interests they have with the company that makes the product? Experts say yes. But it’s a hot issue, and many hospitals haven’t yet taken that step.

Scrutiny by the government and press is fueling the call for disclosure. In 2005, the federal government began investigating consulting relationships between orthopedic companies and surgeons. In July 2006, Medtronic agreed to pay the federal government $40 million to settle accusations that its spinal implant division had paid kickbacks to physicians as a way of inducing use of its products. A Dec 30, 2006, New York Times article discussed a trend by some spine surgeons to profit by investing in companies that sell screws and other devices they use.

All speakers at the American Academy of Orthopaedic Surgeons (AAOS) meeting in February began their talks with a disclosure statement. Though the academy has required disclosure for a long time, the statements are now made aloud. AAOS will soon vote on an expanded code of ethics that is more specific about financial ties.

Last year, the North American Spine Society (NASS) began requiring members to disclose any financial ties for presentations and other society activities. Surgeons we spoke with underscore that collaboration with industry has many benefits that have improved care. They also acknowledge a need for more openness.

“Essentially, what is at stake is public trust,” says Stuart Weinstein, MD, a pediatric spine surgeon and AAOS past president.

NASS president, Richard Guyer, MD, told OR Manager: “The majority of these relationships are extremely positive. But when these relationships exist, the patient needs to be aware of it, or the hospital in the case of purchasing, so it is always aboveboard.

“I think the main issue is transparency,” he continued. “I think an OR has the right to say, ‘Dr Jones, do you have an interest in this company? What is your relationship?’”

Under the NASS policy, physicians must disclose the specific types of arrangements and dollar levels involved, which was the subject of much debate. Dr Guyer says. Physicians must check whether the remuneration is none (less than $250 per year); minor ($250 to $10,000 from all sources); major (greater than $10,000 or more than 5% company ownership).

Dr Guyer says his own practice, the Texas Back Institute with 11 spine surgeons, has adopted a policy of disclosure to patients.

When patients sign in, they get a note stating that during their treatment, the physician may recommend an imaging study or use a product in which the physician has an investment.

“Patients don’t mind,” he says, because it indicates the physician is on the cutting edge of technology. But if patients aren’t told and find out later, it can look bad, he notes.

Orthopedists expand statement

AAOS has proposed expanding its conflict-of-interest statement to be more specific—including an expectation that surgeons will disclose any financial interests to organizations they work with. A vote by members is expected soon, and the revision is expected to pass.
The proposed standards say, for example, that an orthopedic surgeon:

- "who has influence in selecting a particular product or service for an entity shall disclose any relationship with industry to colleagues, the institution, and other affected entities
- "shall disclose to the patient any financial arrangements with industry that relate to the patient’s treatment, including the receipt of inventor royalties, stock options, or paid consulting arrangements with industry
- "shall accept no direct financial inducements from industry for utilizing a particular implant or for switching from one manufacturer’s product to another."

The statements are termed “mandatory minimum standards,” and violations can be grounds for a formal complaint and action by the academy.

Says Dr Weinstein, "We have had a code of ethics for many years. There is really nothing new about that. But we thought we should clarify this for our members so it was less subject to interpretation.” He estimates 98% of board-certified orthopedic surgeons belong to the academy.

**“Drumbeat for disclosure”**

“I think the drumbeat for disclosure is getting louder,” says Charles Rosen, MD, FACS, a spine surgeon and outspoken critic of surgeons’ ties with industry. “It’s coming from the 90% of physicians who are the silent majority. It’s also coming from patients and the law.” He is associate clinical professor of surgery at the University of California, Irvine.

Dr Rosen says he was disturbed enough about conflict of interest that he founded the Association of Ethical Spine Surgeons last year, which has about 200 members (www.ethicalspinesurgeon.org). Members agree not to accept compensation from companies for using any devices the companies make nor to have ownership in a distributorship for spine-care devices.

Dr Rosen says he decided to start the group after treating patients who had problems after receiving the Charité artificial disc. He says the patients came to him after hearing about his criticism of the disc’s design and of the study that led to the Food and Drug Administration’s 2004 approval of the disc. He says the study was flawed because it compared the Charité disc to types of spinal fusion which have since been largely abandoned and did not report all complications.

“I was seeing a lot of patients with disabling symptoms and excruciating pain who had lost their jobs and their houses,” he says. “As I looked into this, I saw that a lot of the physicians pushing this have a financial interest, whether royalties, consulting, or stock options.”

**Bias can creep in**

Physicians asked to disclose their financial arrangements may say, “I would never let that influence my decisions about patient care.”

But studies show industry sponsorship does create bias. The influence is often subtle and may be unconscious, notes Sohail Mirza, MD, an associate professor of orthopedics and neurosurgery at the University of Washington, Seattle, who has written about conflict of interest in orthopedics.

He favors disclosure.

“If the physician stands to personally gain, or use of a device would directly benefit the physician in some way, at the very least, I think patients need to know about that. I personally think that’s a dangerous situation to place oneself in,” he told OR Manager.

Physicians may argue that if they must choose a spinal device, why not pick the one they are most familiar with, even if they stand to benefit?

“I’m not sure that’s an easy decision,” Dr Mirza says. “I think at the very least, patients need to be informed to get a proper informed consent.”

Disclosure to patients probably isn’t happening much at present. In general, he says, conflict-of-interest policies tend to be vague, hard to translate into practice, and inconsistent across institutions.
Awareness increasing

Awareness of conflicts of interest seems to be increasing, Dr Mirza says. He called the new NASS policy “a huge step,” with its requirements to disclose types and amounts of financial arrangements.

The key, he says, will be to strike the right balance between encouraging clinical progress and avoiding damaging types of relationships between companies and physicians. Examples are kickbacks, consulting arrangements where no real work is expected, or distributorships owned by surgeons who commit to use a certain amount of products from the company.

Industry and device studies

Many studies of devices are industry sponsored, which can make them difficult to evaluate. Researchers have found industry-funded research tends to have more favorable results than studies that are independently funded, notes Dr Mirza.

A review by K. A. Ezzet of 603 articles and presentations of orthopedic research found 75% of clinical studies of total hip replacement had commercial sponsorship. In all, 93% of the commercially funded studies had positive outcomes, whereas only 37% of the independently funded studies had good results. Findings were similar for total knee and spinal device research.

This doesn’t necessarily mean the results are deliberately biased, Dr Mirza says. It may be that industry has the resources to fund larger and better studies than other sponsors. It may also be that if a study doesn’t pan out, the company isn’t interested in publishing the results. In a few instances, unfavorable results may be suppressed, which has been the case for some drug trials.

On the plus side, medical journals are adopting more rigorous disclosure policies for research they publish. Guidelines of the International Committee of Medical Journal Editors, updated in 2006, call for participants in peer review and publication to disclose all relationships that could be viewed as a potential conflict of interest (www.icmje.org).

—Pat Patterson

The AAOS proposed statement is at www.aaos.org/industryrelationships.

References


