Patient views on financial relationships between surgeons and surgical device manufacturers

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Background: Over the past decade, revelations of inappropriate financial relationships between surgeons and surgical device manufacturers have challenged the presumption that surgeons can collaborate with surgical device manufacturers without damaging public trust in the surgical profession. We explored postoperative Canadian patients' knowledge and opinions about financial relationships between surgeons and surgical device manufacturers.

Methods: This complex issue was explored using qualitative methods. We conducted semistructured face-to-face interviews with postoperative patients in follow-up arthroplasty clinics at an academic hospital in Toronto, Canada. Interviews were audiotaped, transcribed and analyzed. Patient-derived concepts and themes were uncovered.

Results: We interviewed 33 patients. Five major themes emerged: 1) many patients are unaware of the existence of financial relationships between surgeons and surgical device manufacturers; 2) patients approve of financial relationships that support innovation and research but are opposed to relationships that involve financial incentives that benefit only the surgeon and the manufacturer; 3) patients do not support disclosure of financial relationships during the consent process as it may shift focus away from the more important risks; 4) patients support oversight at the professional level but reject the idea of government involvement in oversight; and 5) patients entrust their surgeons to make appropriate patient-centred choices.

Conclusion: This qualitative study deepens our understanding of financial relationships between surgeons and industry. Patients support relationships with industry that provide potential benefit to current or future patients. They trust our ability to self-regulate. Disclosure combined with appropriate oversight will strengthen public trust in professional collaboration with industry.

Contexte : Ces 10 dernières années, la mise en lumière de relations financières inappropriées entre des chirurgiens et des fabricants de matériel chirurgical a remis en doute la capacité des chirurgiens à collaborer avec les fabricants et ébranlé la confiance du public en la profession. Nous avons étudié ce que les patients canadiens ayant récemment été opérés pensent et connaissent des relations financières entre les chirurgiens et les fabricants de matériel chirurgical.

Méthodes : Nous avons mené une étude qualitative portant sur cette question complexe au moyen d'entrevues semi-dirigées effectuées en personne avec des patients qui assistaient, dans un hôpital universitaire de Toronto (Canada), à des rencontres postopératoires à la suite d'une arthroplastie. Les entrevues ont été enregistrées, transcrites, puis analysées, ce qui a mis au jour des notions et des thèmes issus des patients.

Résultats : Nous avons interrogé 33 patients et dégagé 5 grandes conclusions : 1) de nombreux patients ignorent l'existence de relations financières entre les chirurgiens et les fabricants de matériel chirurgical; 2) les patients acceptent les relations financières qui soutiennent l'innovation et la recherche, mais rejettent celles qui ne profitent qu'aux chirurgiens et aux fabricants; 3) les patients ne veulent pas que les relations financières soient divulguées pendant le processus de consentement, car une telle divulgation pourrait détourner l'attention des risques plus importants; 4) les patients sont d'accord pour qu'une surveillance soit exercée par l'ordre professionnel, mais pas par le gouvernement; 5) les patients font confiance aux chirurgiens et croient qu'ils font des choix axés sur leurs patients.

Conclusion : Cette étude qualitative approfondit notre compréhension des relations financières entre les chirurgiens et les autres acteurs du domaine. Les patients soutiennent ce type de relations pourvu qu'elles puissent profiter aux patients actuels et futurs, et croient en notre capacité d'autoréglementation. Ensemble, la divulgation de ces relations et une surveillance appropriée renforceront la confiance du public en la collaboration entre les professionnels et les entreprises.

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As Plato said, "If you are making flutes, you'd better talk to the flutist."
— Arthroplasty patient

Owing to increasing costs of publicly funded joint replacement surgery, the U.S. Department of Justice (DOJ) launched an investigation in March 2005 into financial relationships between the 5 largest hip and knee implant manufacturers (Biomet, DePuy, Smith & Nephew, Stryker and Zimmer) and orthopedic surgeons.[1] The DOJ alleged that these manufacturers provided unethical financial incentives for orthopedic surgeons to use their products.[2] The financial relationships in question included consulting agreements for questionable work, contracts paying royalties without any actual transfer of intellectual property, payments for continuing medical education at exclusive resorts, expensive meals disguised as medical lectures, inappropriate gifts and even direct payments to surgeons for using specific hip or knee implants.[1]

After 2 years of investigation, the DOJ filed a criminal complaint on Sept. 27, 2007, against 4 of the manufacturers (Zimmer, DePuy, Biomet and Smith and Nephew) for "knowingly and wilfully combining, conspiring, confederating and agreeing with others to commit an offense against the United States by violating the Anti-Kickback Statute."[2] This statute prohibits the exchange of anything of value with the purpose of increasing reimbursement from a federal health program (e.g., Medicare).[2] The complaint was settled through deferred prosecution agreements, which included financial settlements that totalled US$311 million.[2] Although the number of financial relationships between surgeons and manufacturers decreased from 939 to 526 in the year following this settlement, the amount of payments increased from a total of $US198 million to $US228 million.[3] However, this settlement provided the impetus for the Patient Protection and Affordable Care Act (i.e., Sunshine Act), which aims to manage financial relationships between physicians and industry through public disclosure.[4] Central to this U.S. legislation is the requirement that payments of more than $100 made from industry to a physician must be disclosed on a public website.[4]

More recently, surgeon–manufacturer financial relationships have been under scrutiny following the worldwide recall of the DePuy ASRTM Hip[5,6] and the subsequent class action lawsuits.[7] Evidence from the Australian Orthopaedic Association National Joint Replacement Registry indicated that the DePuy ASRTM Hip Resurfacing System had a 5-year revision rate of 10.9% compared with 4% for other prostheses.[6] Initial registry data that suggested this unacceptably high rate of revision were dismissed by the device manufacturer and the surgeon-designers who incorrectly blamed errors in the surgical technique of low volume surgeons as opposed to problems with the implant design.[6,8]

The ASRTM recall provides a potential example of actual patient harm due to bias resulting from financial relationships between a device manufacturer and surgeons.[5,7] The 2 surgeon-designers were named as defendants in the resulting class action lawsuits; they, along with DePuy Orthopaedics, Inc., settled the lawsuits on Nov. 19, 2013, and Mar. 2, 2015.[9,10] These high-profile settlements and legislated disclosure have had little obvious impact on financial relationships between physicians and industry, with US$1.3 billion paid to physicians and teaching hospitals by drug companies and device manufacturers from Aug. 1 to Dec. 31, 2013.[11] During the same time period, US$105 million was paid directly to orthopedic surgeons.[11]

Notwithstanding these aforementioned examples of inappropriate relationships, surgeon–manufacturer financial relationships can benefit both current and future patients. Surgeon collaboration with industry is important for the design and modification of devices as well as for refining surgical techniques and indications for newly developed devices.[12] Surgeon feedback is helpful in anticipating and avoiding potential problems of novel devices and techniques.[12] Surgeon participation is also helpful in the education and training of other surgeons and operating room (OR) personnel in the safe use of new devices.[12] Financial relationships between surgeons and industry can lead to substantial improvements in outcomes and ultimately better patient care. This view is held by even the staunchest critics of surgeon–industry relationships.[1] During the U.S. Senate hearing on this topic, Senator Herb Kohl stated, "these relationships can play an important role in product innovation. In areas where these relationships are legitimate and productive, we do not wish to disturb them."[1]

Trust, credibility and social responsibility that are essential to the surgeon–patient relationship must be enforced and supported by the profession.[13] It remains uncertain how surgeons can continue to have beneficial collaborations with industry while maintaining public trust. In order to maintain public trust, it is important that patients' opinions are explored and incorporated into any recommendations or guidelines.

The purpose of our study was to discover surgical patients' attitudes toward financial relationships between surgeons and device manufacturers. We present the results here to encourage further discussion regarding financial relationships between surgeons and industry and how to benefit from industry partnerships without losing public trust.

Methods

Design

We used qualitative description to discover patient-derived concepts and themes regarding financial relationships between surgeons and surgical device manufacturers.[14]

Setting and participants

Semistructured, face-to-face interviews were conducted with patients who had previously undergone either primary

or revision hip or knee arthroplasty. Participants from 2 surgeons' arthroplasty follow-up clinics at Mount Sinai Hospital, Toronto, Ont., were invited to participate. Mount Sinai Hospital is a tertiary care hospital within a medical system that has a single provincially run medical insurance program. These surgeons' clinics treat a broad spectrum of patients, including those requiring complex revision arthroplasty as well as young adults requiring arthroplasty. Initial interviews were from a convenience sample of patients, but as is common practice with qualitative studies, purposive recruiting began once concepts and themes emerged from data analysis.[15]

We excluded patients who had undergone surgery within 3 months, those who were unable to communicate in English and those who were unable to provide informed consent. Patients were recruited over a 3-month period from January to March 2010. They were enrolled until "saturation" — a theoretical point beyond which no new concepts arise as a result of further interviews — was reached.

Data collection

All interviews were conducted by the first author (M.W.C), who had no therapeutic relationship with the participants, using an interview guide that was developed from a review of the relevant literature. As is customary in qualitative research, the interview guide was iteratively altered based on patient-derived concepts and themes brought out in previous interviews.[16] Interviews lasted 20–45 minutes. They were audiotaped, and demographic information was collected from each participant. All interviews were transcribed verbatim by a professional transcriptionist and were checked for accuracy by M.W.C. Transcriptions were imported into MAXQDA 10 software (Udo Kuckartz) for analysis. This software allows qualitative researchers to organize and code content. Importantly, codes and themes are generated by the researcher, not by the software.

Data analysis

Data were analyzed using qualitative content analysis techniques that included coding in 3 phases. The first phase involved labelling segments of text with conceptual codes derived from the data (e.g., "patient too concerned with pain to deal with other issues"). The second phase involved grouping similar concepts into categories (e.g., "concerns regarding disclosure"). The third phase involved grouping associated categories into identifiable overarching themes (e.g., patients approve of financial relationships that support education and research, but are opposed to relationships that provide benefit solely to the surgeon or manufacturer). Themes described broad concepts that ran throughout the majority of the interviews. Data analysis occurred in parallel to data collection and began after the first interview. As analysis progressed, newly derived codes were defined, linked with other related codes and then applied systematically across previously analyzed data.

In order to verify the trustworthiness of our findings we used several techniques. We confirmed our understanding of participants' statements by paraphrasing and summarizing participant responses to ensure accuracy. By maintaining audiotapes, professionally transcribed interviews and electronically stored data analysis and using verbatim quotes in our results, we created an audit trail that would enable other researchers to follow our decision trail.[17] Although the primary analysis of the transcripts was conducted by M.W.C, this analysis was frequently subjected to critical discussion by the research team and 2 qualitative researchers at the University of Toronto not involved with the study. On 4 occasions, sections of transcripts and analysis were presented to interdisciplinary groups of scholars in law, philosophy, bioethics, medicine, nursing and surgery at the Joint Centre of Bioethics at the University of Toronto. We used the feedback from these groups to develop our analysis.

Ethical considerations

The Research Ethics Board at Mount Sinai Hospital approved our study, and we obtained informed consent from each participant. To ensure confidentiality and privacy, audiotapes were destroyed after transcription. Interview transcripts were rendered anonymous by removing all identifiable information, including the names of surgeons and hospitals, and saved on a password-protected and encrypted computer. Patients were reimbursed $10 for parking. There were otherwise no clinical or material incentives for participation.

Results

Participant information

We interviewed 33 patients before reaching saturation. Participant demographic data are summarized in Table 1.

Qualitative description

Qualitative analysis of the patient interviews yielded 5 patient-derived themes. These themes are described below with verbatim quotes from patient interviews.

Many patients are unaware that financial relationships between surgeons and surgical device manufacturers exist

Despite the publicity in the lay media regarding financial relationships between surgeons and industry,[18–24] the vast majority of patients interviewed were unaware that relationships existed between surgeons and surgical device manufacturers:

"I wouldn't even have thought about that… It wouldn't even have occurred to me." However, more than half of the patients were aware that financial relationships existed between physicians and the pharmaceutical industry: "I've heard somewhere, you know, doctors are paid to promote certain drugs, generally drugs. I have never heard of hip replacements or knee replacements, but definitely drugs."

Patients approve of financial relationships that support innovation and research, but are opposed to relationships that involve financial incentives

Most patients thought that surgeon input is a necessary ingredient for improvement and innovation of surgical devices: "As Plato said, "if you are making flutes, you'd better talk to the flutist."

Regarding educating other health care providers about a company's product, patients felt that this too was a positive relationship: "If that surgeon is helping to teach other surgeons how to use it properly, it's … a good, positive thing, and not a problem."

Many patients treated health care like any other business where financial relationships are essential in advancing the field:

> I don't see there is any difference than in any other industry where practitioners and manufacturers work together. I mean, I don't know how else you are going to end up with better products.

Although most of the patients felt that it is appropriate for surgeons to be reimbursed for their expertise, patients were more discerning when considering relationships that involved providing benefit solely to the surgeon or manufacturer. Importantly, patients disapproved of financial relationships in which there were no foreseeable benefits for current or future patients:

> If he gets paid to educate other surgeons, I think that's in one category…there is something a little hazy about getting a night on the town or free dinners…it doesn't seem like it is in the same category. It seems like it's a step in the other direction...

Most of the patients interviewed judged kickbacks to be inappropriate: "You know, if it is just being used as … a kickback to the surgeon, then I wouldn't agree." Patients were particularly concerned about the prospect of receiving an inferior product because of a relationship based on kickbacks with a particular company:

> If it is for an educational purpose, then… it's productive and if it's really related to work, that's a healthy relationship. But if it's almost like a bribe, or an incentive, that's inappropriate. That would make me uncomfortable, because then it's: 'I am not necessarily going with the best company, I am going with who's spoiling me'.

Patients do not support disclosure of financial relationships during the consent process as it may shift focus away from the more important risks

Most of the patients interviewed do not view disclosure of financial relationships to patients as beneficial. Most patients felt that disclosure would take away focus from other more important preoperative issues:

> I don't think we are knowledgeable enough to know whether it matters. You would just be more confused… you get enough information when you are having something like this done for the first time. I mean, it just clouds the issue. I would rather have not known, to tell you the truth.

Many patients felt that disclosure would merely add to their anxiety: "I don't think they need to have more stress in the decision they are trying to make." Some felt that too much information preoperatively would overwhelm them: "There is too much clutter out there now, there is too much information out there now, and you are just going to confuse people."

Table 1: Participant demographic data

Characteristic	No. of patients
Age, yr	
18–39	1
40–49	3
50–59	8
60–69	12
70–79	7
> 79	2
Sex	
Female	17
Male	16
Employment status	
Working	12
Temporarily off work	3
Retired	17
Marital status	
Single	3
Married	24
Divorced	2
Widowed	4
Educational level	
Some high school	1
High school	3
Some college/university	8
University	12
Graduate/professional school	9
Time since surgery, mo	
3–6	3
7–12	8
13–24	4
25–60	7
61–96	2
≥ 97	9

Many patients felt that a surgeon's business with a device manufacturer should not involve the patient as it would not influence their decision making before surgery: "It's useless information for me, it's not going to help my decision whether to have surgery or not." Many felt that they would have difficulty understanding the complexities of financial relationships between surgeons and industry: "You are into areas where people don't have enough intrinsic training in the field to make use of that information."

Patients support oversight at the professional level but reject the idea of government involvement in oversight

Although they disapproved of disclosure to patients as a method to manage financial relationships, most patients felt oversight was warranted:

> I think it should be looked at…ultimately, it affects the patient, but there is not much the patient can do about [surgeon–industry relationships]. The [professional regulatory bodies] should be the ones that intervene.

Patients felt that the hospital and professional bodies should oversee financial relationships between surgeons and industry:

> I think there has to be really clear conflict of interest policies in the hospitals that cover all departments and they should cover, you know, research practice and any kind of [industry] remuneration in any way for anything, including gifts.

Although all the patients were within a medical system that has a single provincially run medical insurer, patients were against government oversight of financial relationships between surgeons and industry: "I think the government should just stay out of this as much as possible."

Patients' entrust their surgeon to make appropriate patient-centred choices

Patients want decisions regarding the appropriateness of financial relationships with industry to be made by their surgeon. They expect surgeons to make these decisions while holding patients' interests paramount:

> [The surgeon] is the expert, he's probably experimented, he sees which one he thinks works best in individual circumstances and I would think he would use his judgment to pick the one that was most appropriate for my own circumstances.

Regardless of whether they approved of a financial relationship between their surgeon and a device manufacturer, most patients felt that they had little other choice than to trust that their surgeon would place patients' interests above personal financial interests: "But the truth of the matter is…you have to have faith in the person when they cut you open."

Discussion

The results of this study provide needed patient insight and guidance on how surgeons should manage their relationships with industry. Although patients are unaware of relationships between surgeons and industry, more than half of those interviewed were aware of financial relationships between physicians and the pharmaceutical industry. Similar results were found in a survey of Canadian and American hip and knee arthroplasty patients.[25] There are 2 reasons for this phenomenon. The majority of interactions between industry representatives and surgeons do not occur in the vicinity of the conscious patient, whereas interactions between pharmaceutical company detailers and physicians can be noticed by patients in a doctor's office. There has also been a greater emphasis in the lay media on pharmaceutical companies' indiscretions than on those of surgical device manufacturers.

Patients support relationships with industry that provide potential benefit to current or future patients. The patients interviewed in this study did not paint all relationships between surgeons and industry with the same brush. They viewed relationships in which a surgeon's knowledge and experience is required for product innovation and education differently from those that offer no potential benefit to current or future patients. Patients acknowledged that surgeon input is vital in the development and improvement of surgical treatments. They supported surgeon engagement and reimbursement by device manufacturers for their expertise. These findings are consistent with those of quantitative research examining patient views on surgeons as industry consultants[25,26] and physician–industry relationships.[27–29]

In an effort to manage financial relationships between surgeons and device manufacturers, the U.S. Patient Protection and Affordable Care Act mandated public reporting of financial relationships between physicians and pharmaceutical companies and device manufacturers.[4] It is unclear how this information will be used by individual patients. The patients we interviewed felt that financial relationships were difficult to comprehend and that they would distract from the surgical risks outlined during the consent discussion. As Weinfurt and colleagues[30] found in their 2008 study, conflicts of interest rank low on patients' decision-making priority lists. Our findings are in contrast to the results of a review of quantitative studies that reported a strong patient desire for disclosure.[31] This review included studies that did not examine vulnerable patients facing major surgical risks as a component of their decision-making process. Most of the studies reviewed used potential patients, potential research participants or members of the general public, who had few, if any, competing worries. Patients in our study had an outlook similar to those of more vulnerable research participants surveyed in cancer research trials.[32,33] Vulnerable research participants often rejected the idea of disclosure, as they felt it did

not help them in the decision to participate, and it added an extra burden that they would rather not deal with.[32] Our study patients endorsed this view. Like cancer trial participants, surgical patients have limited options and are the least likely to use information regarding their surgeon's financial relationships with industry in their preoperative decision making.[33]

Though our study participants supported oversight of financial relationships between surgeons and industry, they rejected government involvement. Our data are consistent with previously published data using quantitative methods, suggesting that patients feel that professional self-regulation is appropriate and that the profession can be trusted with the management of members' conflicts of interests.[25]

Ultimately, patients trust their surgeons to make decisions that prioritize patients' interests. Regardless of whether they wanted disclosure or approved of financial relationships, patients in our study expected their surgeons to manage conflicts of interests appropriately and ethically. Patients do not want their relationships with their surgeons to dissolve into a "buyer beware" model. They expect their surgeons to make decisions regarding conflicts of interest based on the surgeons' knowledge, integrity and virtue. The data derived from this qualitative analysis are consistent with peer-reviewed published quantitative analyses.[25]

Limitations

Our study has several limitations. As we interviewed a single surgeon's patients from a single urban academic hospital within a medical system that has a single provincially run medical insurer, the views provided may not be generalizable to patients in other settings. Patients who agreed to participate may have divergent views from those who did not participate. Postoperative patients' trust in their surgeon may have influenced their responses, and patients may have been biased by their positive outcomes. However, we excluded patients who had experienced complications or poor outcomes. We excluded preoperative patients to minimize the risk of inducing worry and mistrust that might be caused by discussing this topic preoperatively. Although the interviewer had no professional relationships with the patients interviewed, he was an orthopedic trainee at the time of the interviews while concurrently completing a Master of Science in bioethics. This potential source of bias was mitigated by having 2 qualitative researchers at the University of Toronto critically examine the data analysis. In addition, on 4 seperate occasions, sections of transcripts and analysis were presented to interdisciplinary groups of scholars in law, philosophy, bioethics, medicine, nursing and surgery at the Joint Centre of Bioethics at the University of Toronto. Feedback from these groups was used to develop our analysis.

Conclusion

This qualitative study deepens our understanding of financial relationships between surgeons and industry. Patients support relationships with industry that provide potential benefit to current or future patients. They trust our ability to self-regulate. Disclosure is a necessary but insufficient strategy to manage conflicts of interest. Disclosure combined with appropriate oversight will strengthen public trust in professional collaboration with industry.

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