Patient Views on Financial Relationships between Orthopaedic Surgeons and Orthopaedic Device Manufacturers

by

Mark Wickus Camp

A thesis submitted in conformity with the requirements for the degree of Master of Science
Institute of Medical Science/Joint Centre for Bioethics
University of Toronto

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2011

Abstract

Revelations of kickbacks from surgical device manufacturers to orthopaedic surgeons raise the question whether surgeons can continue to collaborate with industry and maintain public trust. Using qualitative and quantitative methodology, this thesis explores U.S. and Canadian surgical patients’ views on financial relationships between surgeons and surgical device manufacturers and patients’ recommendations for managing these conflicts of interest.

A majority of patients approve of surgeon’s relationships with manufacturers that can benefit patients but disapprove of those that primarily benefit the surgeon and the manufacturer. The majority of patients do not endorse disclosure as a sole method of managing these relationships. The majority of patients continue to trust the surgical profession to self-regulate and favour oversight by the profession rather than by government to ensure financial relationships between surgeons and manufacturers are appropriate.

My data supports my argument that there should be professional oversight of financial relationships between surgeons and manufacturers, which may allow continued collaboration with manufacturers while maintaining public trust.
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<tr>
<td>AAOS</td>
<td>American Academy of Orthopedic Surgeons</td>
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<tr>
<td>AMA</td>
<td>American Medical Association</td>
</tr>
<tr>
<td>CJRR</td>
<td>Canadian Joint Replacement Registry</td>
</tr>
<tr>
<td>CMA</td>
<td>Canadian Medical Association</td>
</tr>
<tr>
<td>CPSO</td>
<td>College of Physicians and Surgeons of Ontario</td>
</tr>
<tr>
<td>NIH</td>
<td>National Institutes of Health</td>
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<tr>
<td>PPAC</td>
<td>Patient Protection and Affordable Care Act</td>
</tr>
<tr>
<td>US</td>
<td>United States</td>
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<tr>
<td>U.S.</td>
<td>United States (when used as an adjective, e.g. U.S. Senate)</td>
</tr>
<tr>
<td>U.S. DOJ</td>
<td>United States Department of Justice</td>
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1 Introduction

1.1 The problem

In 2007 the surgical community was shocked by massive kickback scandals, the consequences of which have yet to be fully realized. In March 2005, in response to escalating costs to U.S. Medicare from hip and knee replacement surgery, the U.S. Department of Justice (DOJ) launched an investigation into financial relationships between the five largest hip and knee replacement manufacturers (Biomet, DePuy, Smith & Nephew, Stryker and Zimmer) and orthopaedic surgeons (Surgeons for sale: Conflicts and Consultant Payments in the Medical Device Industry, 2008 [hereafter cited as Surgeons for sale, 2008]). Following this investigation, the U.S. DOJ filed a criminal complaint against four major orthopaedic device manufacturers (Zimmer, DePuy, Biomet, 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” (Christie, 2007). Alleged kickbacks between surgeons and device manufacturers brought to light during the subsequent U.S. senate hearing included: lucrative consulting agreements for which minimal work was actually performed, contracts paying royalties without any transfer of intellectual property, inappropriate gifts, and even direct payments to surgeons for using a specific manufacturer’s device (Surgeons for sale, 2008). The complaint against Biomet, DePuy, Smith & Nephew and Zimmer was ultimately settled through deferred prosecution agreements which included financial settlements that totalled US$311 million (Christie, 2007).

Due to increased U.S. government surveillance, the U.S. DOJ investigation has resulted in a decrease in all financial relationships between orthopaedic surgeons (hereafter referred to as surgeons) and surgical device manufacturers (hereafter referred to as manufacturers) (Marra, 2009). Manufacturers have curtailed all interactions with surgeons in an attempt to avoid any financial relationship that could be viewed as a kickback (Healy & Peterson, 2009). This has had the desired effect of not only restricting inappropriate financial relationships between surgeons and manufacturers but also restricting those surgeon-manufacturer collaborations that may be viewed as beneficial (Surgeons for sale, 2008).
Surgeon involvement with manufacturers is important for developing and fine-tuning surgical techniques and indications for newly developed devices (Jacobs, Galante, Mirza, & Zdeblick, 2006). Surgeon feedback is crucial in anticipating and avoiding potential problems of novel devices and techniques (Jacobs et al., 2006). Surgeon participation is also helpful in the education and training of other surgeons and operating room personnel in the safe use of new devices (Jacobs et al., 2006). Financial relationships between surgeons and manufacturers can lead to substantial improvements in outcomes and ultimately better patient care.

Even the staunchest critics acknowledge the value of surgeon-manufacturer collaborations (Surgeons for sale, 2008). Bringing a product to market is too costly to be done by independent surgeons or academic institutions and therefore patents are either developed with device manufacturer financial support or sold to the manufacturer in return of royalties (Brande, Buckwalter, Talman, & Happe, 2003; Jacobs et al., 2006). Prohibition of all financial relationships between surgeons and manufacturers, therefore, has not been proposed as a method to appropriately manage these relationships (Surgeons for sale, 2008).

Rather, the U.S. government has opted for disclosure via publically accessible websites as a method to discourage inappropriate kickbacks while allowing beneficial surgeon-manufacturer collaboration (Patient Protection and Affordable Care Act, 2010 [here after cited as PPAC, 2010]). By September 30th, 2013, financial relationships between U.S. health care providers and industry will be available on publically searchable websites. No further oversight has been legislated leaving the burden of processing disclosure of financial relationships between surgeons and manufacturers squarely on the shoulders of patients.

Empirical evidence that explores disclosure to patients as an effective method of managing financial relationships between health care providers and industry is inconclusive. Research studies that support disclosure use opinions from potential patients, members of the public (Mainous, Hueston, & Rich, 1995; Crigger, Courter, Hayes, & Shepherd, 2009; Jastifer & Roberts, 2009; Edwards & Ballantyne, 2009) or potential research participants (Kim, Millard, Nisbet, Cox, & Caine, 2004; Weinfurt et al., 2006; Weinfurt et al., 2008) as surrogates for patient opinions. It is unclear if conclusions from these surrogate samples can be generalized to surgical
patients. These surrogates have few, if any, competing thoughts or worries in contrast to patients facing surgery. Surgical patients’ opinions about financial relationships between surgeons and manufacturers may actually be more closely aligned to the opinions of other vulnerable patient groups, such as the opinions of cancer patients enrolled in research trials. Opinions of research participants enrolled in cancer trials indicate that disclosure of a researcher’s financial relationships with industry may only be wanted by a minority of participants (Hampson et al., 2006).

Like research participants with cancer, surgical patients place enormous trust in their health care providers (McKneally & Martin, 2000). This trust may limit the effectiveness of disclosure to patients as a method to manage financial relationships between surgeons and manufacturers. It has been suggested that it is psychologically advantageous for vulnerable patients to trust that their health care provider would not let financial relationships with manufacturers influence the care of the patient (Hampson et al., 2006). Disclosure alone, without other oversight measures, may be insufficient to prevent inappropriate kickbacks.

Mediated oversight remains a feasible method of managing financial relationships between surgeons and manufacturers. Using utilitarian calculus, oversight committees at a hospital, professional or government level could ensure that financial relationships are managed in a way that maximizes patient outcomes but minimizes risk to patient trust. Utilitarianism is a normative ethical theory that maintains that the morally correct action is the one that promotes the greatest amount of happiness for the greatest number (i.e. utility) (Arras, Steinbock, & London, 1999, p. 9). Consequences are the only relevant feature in determining what is morally right and decisions are made to maximize utility (Arras et al., 1999). As such, a rule utilitarianism approach to managing financial relationships between surgeons and manufacturers would mandate that a relationship between a surgeon and a device manufacturer would be morally acceptable if and only if it conforms to a rule whose observance would maximize utility (Waluchow, 2003, p. 145).

Using rule utilitarianism, morally unacceptable (i.e. inappropriate) financial relationships between surgeons and manufacturers may be considered as those financial relationships that
provide benefits solely to the surgeon or manufacturer without any benefit to current or future patients. These financial relationships do not maximize utility as the utility from improved surgeon and manufacturer finances is outweighed by the disutility from possible decreased patient trust in the surgical profession, increased product costs and unnecessary surgical treatment. In contrast, morally acceptable (i.e. appropriate) financial relationships between surgeons and manufacturers may be considered as those financial relationships that have the potential to improve current or future patient care as they maximize utility. The disutility from decreased patient trust in the surgical profession, increased product costs and unnecessary surgical treatment is outweighed by the utility from improved patient outcomes and improved surgeon and manufacturer finances.

Accusations of kickbacks between surgical device manufacturers and surgeons have damaged the reputation of the surgical profession. Trust, credibility and social responsibility are essential features in the surgeon-patient relationship, and they must be enforced and supported by the profession in order to maximize utility (Cooney, 2007). If the surgical profession is to maintain patient trust to maximize utility, patient views and opinions need to be explored and taken into account in any mediated oversight of financial relationships between surgeons and manufacturers. This will help ensure that surgeons are interacting with device manufacturers in a manner that patients feel is appropriate; maximizing utility by maintaining patient trust while advancing medicine through collaborations with manufacturers.

This thesis explores surgical patient attitudes towards financial relationships that can exist between surgeons and device manufacturers. In particular, this thesis provides insight into: whether surgeons can collaborate with manufacturers while maintaining patient trust; which types of financial relationships, if any, patients feel are appropriate; and which methods of management of financial relationships (i.e. prohibition, mediated oversight, or disclosure) between surgeons and manufacturers should be embraced to maintain patient trust in our profession.
1.2 Why use qualitative and quantitative methods?

Qualitative methodology, long recognized by social scientists, enables a researcher to gather participants’ views on questions about how and why phenomena occur (Pope & Mays, 1995). In contrast, quantitative methodology, well known to biomedical scientists, addresses how many and what phenomena occur. Quantitative research sacrifices depth and complexity for accuracy and generalizability. Qualitative methods are of particular value when examining areas not amenable to quantitative methods, such as complex social phenomena with multiple variables that are difficult to control (e.g. beliefs, behaviours and attitudes) (Pope & Mays, 1995).

Qualitative methods may also be used to improve subsequent quantitative methods in the study of a particular phenomenon (Pope & Mays, 1995). For example, qualitative interviews may uncover previously unknown aspects of a particular phenomenon of interest. These aspects can then be explored using a quantitative method, ultimately improving the survey’s content validity. The use of qualitative research is common in other biomedical fields. The nursing profession, for example, disappointed with the lack of applicability of quantitative methods, has wholeheartedly adopted qualitative methods to explore the complex issues seen in their profession (Thome, Kirkham, & MacDonald-Emes, 1997).

A qualitative study is well-suited to investigate the complex issue of patient views on financial relationships between orthopaedic surgeons and orthopaedic device manufacturers. However, Ovid Medline, Embase and Scopus literature database searches, performed on October 13 2010, using the key phrase, “qualitative research” in both the Journal of Bone and Joint Surgery American and British volumes, yielded only 1 article out of a total of 9592 articles. These results demonstrate the disregard of qualitative research in the field of orthopaedic surgery. Therefore, following my qualitative study, a quantitative study was completed. The familiarity that orthopaedic surgeons have with quantitative methods will allow greater impact and acceptance of my findings. I was able to enhance the content validity of my quantitative survey by using the patient-derived concepts and themes from a qualitative study.

When considering this research, I am cognizant of the question that was first posed by David Hume, “is it possible for a proposition expressing a moral judgement (ought) to be deduced from
a proposition or set of propositions which do not possess moral judgements (is)” (McGrath, 1975, p. 150). Put another way, finding that patients approve of their surgeon receiving gifts from a device manufacturer, does not necessarily mean that receiving gifts from a device manufacturer is morally acceptable. However, the results of my research may improve the accuracy of utilitarian calculus in determining which financial relationships maximize utility and should be permitted and which financial relationships do not maximize utility and should either be prohibited or mitigated via other measures (e.g. disclosure).

1.3 Organization of thesis

The thesis is organized as the research was conducted. A literature review is incorporated in the Background. Literature pertaining to qualitative and quantitative methods is discussed in the respective methods sections. As both the qualitative and quantitative studies are considered stand-alone research studies, each set of results is followed by a discussion section. A final combined conclusion provides my opinions on how surgeons’ relationships with manufacturers should be managed in Canada and what further research needs to be performed to ensure that these proposals are implemented responsibly.
2 Background

2.1 Kickback scandals in orthopaedic surgery

More than 800,000 hip and knee replacement surgeries were performed in North America in 2005 (Canadian Joint Replacement Registry [CJRR], 2009; DeFrances & Hall, 2007). This rate is expected to rise above 1.5 million by 2015 (Kim, 2008). In the United States (US), approximately two-thirds of these surgeries are paid by Medicare or Medicaid, placing an increasing burden on the U.S. federal health insurance system (Kim, 2008). Due to the increasing costs attributed to joint replacement surgery the U.S. Department of Health and Human Services Office of the Investigator General became suspicious of orthopaedic surgeons’ close relationship with manufacturers (Surgeons for sale, 2008). Therefore, in March 2005, the U.S. Department of Justice (U.S. DOJ) launched an investigation into financial relationships between the five largest surgical device manufacturers that make hip and knee replacements (Biomet, DePuy, Smith & Nephew, Stryker and Zimmer) and orthopaedic surgeons. The U.S. DOJ alleged that these manufacturers provided unethical financial incentives to surgeons to use their products (Christie, 2007). Alleged kickbacks between surgeons and device manufacturers brought to light during the subsequent U.S. Senate hearing included: lucrative consulting agreements for which minimal work was actually performed, contracts paying royalties without any transfer of intellectual property, inappropriate gifts, and even direct payments to surgeons for using a specific manufacturer’s device (Surgeons for sale, 2008).

These five manufacturers represent more than 90% of the $12 billion hip and knee implant market in the US and Canada (Surgeons for sale, 2008). In 2007 alone, these five manufacturers paid US$272 million to surgeon consultants for royalties based on product development and design, teaching, clinical research and travel expenses (Marra, 2009). Of concern, the U.S. DOJ found little or no work was performed to justify many of these payments to surgeons (Surgeons for sale, 2008). For example, during regular surgeries, a company sales representative would spend the day in the operating room observing and then pay the surgeon for 8 hours of “training” (Surgeons for sale, 2008, p. 11). “Some of these training sessions were held for experienced sales representatives who, as part of their jobs, had been servicing the surgeons in their sales regions for some time. These sales representatives were already required to be present
in the operating room with the surgeons to assist them with the procedures. These training sessions lasted for 1-2 hours, but the consultants (i.e. surgeons) billed for an 8-10-hour workday” (Surgeons for sale, 2008, p. 11).

After 2 years of investigation, the U.S. DOJ filed a criminal complaint on the 27th of September 2007 against four of the manufacturers (Zimmer, DePuy, Biomet, Smith and Nephew) for “knowingly and willfully combining, conspiring, confederating and agreeing with others to commit an offense against the United States by violating the Anti-Kickback Statute” (Christie, 2007). The complaint was settled through deferred prosecution agreements, which included financial settlements that totalled US$311 million (Christie, 2007). Importantly, the deferred prosecution agreements required disclosure of financial relationships between manufacturers and surgeons. From 2007 to 2009 each manufacturer was required to post prominently on its web site the names and the amount of payment for all physicians who were and are currently paid by the company (Surgeons for sale, 2008).

Following this investigation, manufacturers have curtailed sponsored research, educational activities funding and university program funding in attempt to avoid any financial relationship that could be viewed as kickbacks (Healy & Peterson, 2009). The total consulting payments from the aforementioned manufacturers dropped from $272 million in 2007 to $105 million in 2008 (Marra, 2009). The total number of surgeons with financial relationships with these manufacturers dropped from 1693 in 2007 to 628 in 2008 (Marra, 2009). The scrutiny placed on these orthopedic device manufacturers has had an obvious impact on the previous “carte blanche” use of surgeon consultants. In testimony at the U.S. Senate hearing into this scandal, a Zimmer representative stated: “When we are consulting with health care professionals, it is to address one of three things and only one of three things. That is, patient safety, improved outcomes and addressing unmet clinical needs” (Surgeons for sale: Conflicts and Consultant Payments in the Medical Device Industry, 2008, p. 75).

Although this scandal was uncovered in the US, it would be naive to believe that these relationships are isolated to that country. There is no evidence to suggest that relationships between these multinational manufacturers and Canadian surgeons are different than those in the
US. It would be imprudent to believe that kickbacks are isolated to the US, particularly when the same five aforementioned manufacturers hold the same market share in Canada and have the same corporate and marketing structure in this country as in the US.

2.2 Types of relationships between surgeons and manufacturers

Jorge Galante has classified the types of financial relationships that do exist between surgeons and a manufacturer (Jacobs, Galante, Mirza, & Zdeblick, 2006). Galante’s classification enables a better comprehension of these financial relationships and allows for a more nuanced approach to manage them.

**Type 1:** A surgeon may possess intellectual property and hold a patent on a product for which the orthopaedic device manufacturer pays royalties to the surgeon (Jacobs et al., 2006). For example, a surgeon may develop a new screw design and patent the concept. The device manufacturer would then pay royalty fees to the surgeon for incorporating the new screw design in their line of products.

**Type 2:** A surgeon may perform work that requires the surgeon’s particular expertise for the device manufacturer (Jacobs et al., 2006). For example, a surgeon may help the manufacturer to improve the design of a hip replacement based on the problems the surgeon has faced with the existing replacement intra-operatively.

**Type 3:** A surgeon may perform promotional activities for a manufacturer (Jacobs et al., 2006). These activities could include presentations or hands-on demonstrations to other health care professionals about a manufacturer’s products. These “surgeon champions” are often highly regarded surgeons used as product “endorsers” (Kostiuk, 2007, p. 549). Dr Augusto Sarmiento, one the orthopaedic field’s most highly regarded surgeons, was approached by an orthopaedic device manufacturer with an offer of $250 000 for the naming rights of a new hip prosthesis (Sarmiento, 2003). Dr Sarmiento declined the offer because he had not been involved in the design or development of the prosthesis (Sarmiento, 2003). Interestingly, the prosthesis was eventually named after another high profile orthopaedic surgeon who, like Dr Sarmiento, had not been involved in the design of the prosthesis but had accepted the payment (Sarmiento, 2003).
Type 4: A surgeon, like many other health care professionals, can have financial relationships with orthopaedic device manufacturers that involve incentives to use the manufacturer’s products (Jacobs et al., 2006). These incentives can include gifts such as textbooks, meals and travel bursaries. These gifts are intended by the manufacturer to build a reciprocal relationship with the surgeon. However, some incentives are more blatant in attempts to boost a device manufacturer’s market share. Sarmiento provides an example of these incentives:

“While serving as chairman of the Department of Orthopaedics at the University of Southern California, I was offered by a representative from industry money for every total joint implant done at its five affiliated hospitals. On my rejection of the lucrative deal, the industry representative responded that such arrangements “were common and acceptable practices” (Sarmiento, 2003, p. 41-42).

2.3 Definition of Conflicts of Interest

Although difficult to define, fiduciary relationships are those in which one member (the fiduciary) of the relationship is entrusted with an item of value on behalf of the other member (the beneficiary) of the relationship (Morreim, 2010). In the surgeon-patient relationship, the surgeon (the fiduciary) is entrusted with the health of the patient (the beneficiary). Critically, the surgeon holds discretionary power over the patient’s health and it is difficult for the patient to monitor the surgeon’s actions (Morreim, 2010). This difficulty to monitor is due to the inferior knowledge and vulnerability of the patient. Practically, surgical patients have the obvious additional barrier of being under anaesthesia during the procedure. For these reasons, “strong duties of loyalties are imposed” (Morreim, 2010, p. 15).

Fiduciary law maintains that fiduciaries “must act solely in the beneficiary’s interest, thereby effacing self-interest and refraining from exploiting the beneficiary's vulnerability” (Morreim, 2010, p. 15). It is here where I depart from treating the patient-surgeon relationship like a classic fiduciary-beneficiary relationship. The use of the word “solely” in the previous sentence imposes an excessive and unrealistic burden on physicians and surgeons. However, this concept is expressed in many medical associations’ codes of ethics (Canadian Medical Association [CMA], 2004; American Medical Association [AMA], 2010, and College of Physicians and Surgeons of
Ontario [CPSO], 2008). For example, the CPSO maintains that’s “in all situations where a conflict of interest arises in the course of professional duties and activities, physicians should recognize the conflict, ensure that the patient’s best interests remain paramount” (CPSO, 2008). Although I agree with the sentiment of these statements, they oversimplify the concept of conflict of interest. In their chapter in Surgical Ethics, Khushf and Gifford define a conflict of interest as a “situation in which the self-interest of an individual is in tension with an obligation” (Khushf & Gifford, 1998, p.347). As opposed to other definitions of this complex concept (Beauchamp & Childress, 2009), this definition appropriately allows physicians and surgeons to evaluate their personal interests against their obligations. Providing care to a patient is not the sole obligation of a surgeon. Surgeons can have other obligations that include: the education of future and current health care professionals, the containment of costs, and the integrity of the profession (Wendler, 2010). For example, in a socially funded health care system, surgeons have an obligation to contain costs. It is in the best interest of an elderly patient that has suffered a femoral neck fracture, once medically optimized for surgery, to undergo fracture fixation as soon as possible. This has clearly been demonstrated in the literature (Simunovic et al., 2010).

However, a surgeon’s obligation to contain costs prohibits the running of multiple after-hours operating rooms simultaneously. Patients wait in the queue for their turn in the operating room and more operating rooms are made available only when irreversible harm will occur to a patient if their surgery is delayed. Surgeons manage these competing obligations and interests daily.

A surgeon’s personal interests can include fame, fortune and career advancement. Personal interests should not trump a surgeon’s professional obligations. These obligations are determined by the covenant that surgeons enter into with society upon their graduation from medical school (Allman, 2003). Surgeons are “parties to a covenant both with society, which grants the privilege” (Levinsky, 2002, p. 761) to perform surgery, and with patients who entrust their surgeon to “judiciously balance the patient’s interests” and those of competing interests (Pelligrino, 1992, p. 362). Since the actions of an individual can affect the entire profession, each surgeon has an obligation to make sure their own conduct does not impair their “colleagues’ capacity to practice medicine or conduct research” (Thompson, 2003, p.574).
It must not be interpreted that surgeons, as fiduciaries, cannot pursue their personal interests. Surgeons may legitimately receive compensation for work performed (Rodwin, 1995). However, the profession must ensure that a surgeon’s personal interest does not dominate the obligations of the profession (Thompson, 2003). This would not maximize utility as the utility from a surgeon’s personal interest would be outweighed by the disutility caused by the damage to patients’ trust in the profession. This concept is central to the limits to surgeon consulting agreements set out in the US Anti-Kickback statute, where surgeons are entitled to a maximum of $500/hr for work performed on behalf of manufacturers (Surgeons for sale, 2008). By limiting reimbursement to $500/hr, the utility from the surgeon’s financial gain is diminished but as there is less damage to patients’ trust in the profession, disutility is decreased and utility is maximized.

2.4 Strategies to manage conflicts of interest

If surgeons do not voluntarily manage their conflicts of interest appropriately, legislative bodies will impose their solutions (Steinbrook, 2009). U.S. legislators have already imposed their own solution on the U.S. medical community. The U.S. Senate and House of Representatives passed the Patient Protection and Affordable Care Act in 2010 (Patient Protection and Affordable Care Act, 2010 [here after cited as PPAC, 2010]). This act contains the Physician Payment Sunshine Provision (PPAC, 2010). This provision aims to increase transparency of financial relationships between health care providers and industry. This act mandates that any financial relationship between a surgical device manufacturer and surgeon or academic institution be reported to federal authorities (PPAC, 2010). These relationships will be available on a publically-searchable website by September 30th 2013 (PPAC, 2010). Reportable financial relationships will be mandatory for any payment over $10 (PPAC, 2010). The aforementioned kickback scandals and evidence presented in subsequent sections in this thesis indicate that not all surgeons are capable of ensuring that their financial relationships with manufacturers are appropriate. In order to maximize utility, the surgical profession must work to establish methods to manage these financial relationships so that patient trust can be maintained and beneficial collaborations with manufacturers can continue.

Strategies for the surgical profession to manage their conflicts of interest have been described: prohibition, education, mediated oversight, and disclosure (Thompson, 2003; McKneally, 2007).
Different conflicts of interest may require different methods of management. Certain relationships are blatantly inappropriate as they clearly do not maximize utility; for example, those that obviously risk loss of patient trust or risk the use of inferior products without advancing any socially worthy goal should be prohibited through legislation. As another example, direct payments to surgeons to use a particular prosthesis jeopardize the public’s trust in orthopaedic surgeons and do not advance research, education or the care of current or future patients. Examining patient views on which financial relationships jeopardize public trust may be helpful in determining which financial relationships should be prohibited.

Other financial relationships may jeopardize public trust in surgeons but may advance a socially worthy goal. For example, financial relationships between surgeons and manufacturers that encourage novel and improved surgical treatments might be best managed through mediated oversight. Society should not stifle scientific advancement. However, the profession should make sure that scientific advancement is not trumping the care of the patient. The trustworthiness of the profession could be strengthened if professional organizations, through conflicts of interest committee, ensured that interests of scientific advancement were not undermining the interest of patients.

Legislators and lawyers use disclosure as the fallback position with regards to managing conflicts of interest (PPAC, 2010). Public disclosure alone may be an ineffective and inappropriate method of managing these complex financial relationships between surgeons and device manufacturers. Firstly, disclosure of conflicts of interest to patients may overwhelm an already anxious patient (Grady, Horstmann, Sussman, & Hull, 2006). Secondly, disclosure may take the patient’s focus away from the significant surgical consequences and surgical risks they need to come to terms with during the consent procedure. Finally, patients may not have the knowledge or ability to determine how their surgeon’s financial relationships will impact their care (Weinfurt et al., 2006). However, legislation is required to mandate disclosure of surgeon financial relationships to committees at the hospital or professional organization, with the appropriate knowledge and skills to monitor these relationships.
Now I will consider in turn, the conflicts of interest management strategies of prohibition, education, mediated oversight, and disclosure.

2.5 Prohibition as a method of managing financial relationships with manufacturers

Prohibition of all financial relationships between surgeons and manufacturers would result in the loss of socially worthy benefits of the surgeon-manufacturer relationship. Lichter argued that there needs to be a distinction between financial relationships that benefit only the surgeon or the manufacturer and financial relationships that promote socially worthy pursuits (e.g. research) (Lichter, 2008).

Surgeon relationships with manufacturers are important for developing and fine-tuning surgical techniques and indications for newly developed devices (Jacobs et al., 2006). Moreover, surgeon feedback is crucial in anticipating and avoiding potential problems of novel devices and techniques (Jacobs et al., 2006). Surgeon participation is also helpful in the education and training of other surgeons and operating room personnel in the safe use of new devices (Jacobs et al, 2006). These relationships can lead to substantial improvements in outcomes and ultimately better patient care. This view is held by even the staunchest critics of surgeon-manufacturer relationships (Surgeons for sale, 2008). In the recent U.S. Senate hearing on this topic U.S. Senator Herb Kohl said, “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” (Surgeons for sale, 2008, p. 1). Senator Kohl, along with Senator Grassley, introduced the Physician Payment Sunshine Provision (PPAC, 2010).

Due to the enormous costs of bringing a new device or surgical implant to market, collaboration with orthopaedic device manufacturers is necessary for further progress in the field of orthopaedic surgery and in the treatment of patients with musculoskeletal disease. These necessary relationships have to be closely monitored. Previous research suggests that industry-funded studies are more likely to be associated with statistically significant pro-industry findings (Ezzet, 2003, Bhandari et al., 2004). Some recent research, however, does not support these findings (Noordin, Wright, & Howard, 2010). There may be a difference between papers
presented at meetings and those that have undergone peer-review, with the process of peer-review analyzing pro-industry results critically (Okike, Kocher, Mehlman & Bhandari, 2007; Noordin et al., 2010). All of these studies do demonstrate, however, the continued need to monitor financial relationships, even those relationships that support socially worthy goals. Monitoring will ensure that professional obligations to patients and society’s interests are not being trumped by the interests of the surgeon or the manufacturer.

Using rule utilitarianism, it is ethically responsible to prohibit any financial relationships that do not obviously promote the surgeon’s obligations to patients’ or society’s interests as utility will not be maximized (Thompson, 2003). Surgeons need guidance in how to ethically balance their financial relationships with manufacturers such that these financial relationships with manufacturers do promote their obligations to patients and society’s interests thereby maximizing utility. Jorge Galante sums up the issue stating, “The ideal model should be one that allows productive collaboration without the hint of real or perceived bias” (Jacobs et al, 2006, p. 1653).

2.6 Education and mediated oversight as methods of managing financial relationships with manufacturers

Huddle explored the arguments for the prohibition of relationships between physicians and pharmaceutical detailers (Huddle, 2010). Huddle disagrees with these arguments as they place too much emphasis on behaviour economics literature (Huddle, 2010). The behaviour economics literature emphasises the persuasive nature of industry’s interactions with physicians and therefore may lead to inappropriate prescribing (Huddle, 2010). Examining the finance literature instead, Huddle determined that the informative (i.e. socially worthy) effects of physician-pharmaceutical detailer relationships are primary, with the persuasive effects of these relationships very much secondary (Huddle, 2010). Talking about the calls to ban pharmaceutical detailing, Huddle writes, “We could have that kind of moral clarity about pharmaceutical detailing only if physician engagement with it was known to be inevitably always harmful” (Huddle, 2010, p.4). He argues that a better policy would ensure that health care professionals process detailing better rather than completely banning the practice (Huddle, 2010).
However, a relationship may not need to be always harmful to require prohibition. In order to maximize utility, patient trust must be maintained. The profession should, therefore, ensure that personal interests do not dominate or appear to dominate professional obligations. Research by Chren and Landefeld demonstrated that physicians who had made a formulary request were more likely to have taken a gift from industry (Chren & Landefeld, 1994). Formulary requests were independent of the merits of the company’s product. This research suggests that financial relationships between surgeons and manufacturers where the surgeons are given gifts have the potential to dominate professional obligations. A gift from a manufacturer to a surgeon neither promotes the professional’s obligation to patients nor the interests of society.

Despite the shortcomings of Huddle’s argument (Huddle, 2010), important questions are raised. Can a policy be implemented to ensure that surgeons process detailing or financial relationships with manufacturers better? On a broader scale, should policies be implemented that rely on individual surgeons to manage their own conflicts of interest?

Education of medical residents regarding the potential conflicts of interests resulting from financial relationships between physicians and industry has been attempted and has demonstrated moderate success (Keim, Sanders, Witzke, Dyne, & Fulginiti, 1993; Hopper, Speece, Musial, 1997; McCormick, Tomlinson, Brill-Edwards, & Detsky, 2001; Schneider, Arora, Kasza, Van Harrison, & Humphrey, 2006). Keim et al. surveyed 1385 emergency medicine residents and found that their understanding of conflicts of interest was correlated with the amount of bioethical education during residency (Keim et al, 1993). Furthermore, this understanding was correlated with behaviour (Keim et al, 1993). Hopper et al. tested the effects of a 40 minute presentation and discussion of physician-industry relationships on the attitudes of 31 medical residents (Hopper et al., 1997). Following the presentation, residents were more likely to find that relationships that provide no social benefit may be inappropriate and that industry marketing techniques may negatively influence their prescribing habits (Hopper et al., 1997).

McCormick et al. examined the influence of a strict policy restricting resident interactions with industry representatives (McCormick et al., 2001). In 1992, McMaster University instituted a policy that restricted resident-industry interactions. Industry representatives were banned from
attending or sponsoring lunch-time educational rounds (McCormick et al., 2001). McMaster University residents were compared to previous McMaster University residents, who trained prior to the policy, and University of Toronto residents, where no such policy existed. McCormick et al. found that a physician’s current contact with industry representatives was correlated to frequency of contact during residency (McCormick et al., 2001).

Schneider et al. used workshops to educate medical residents about potential problems with financial relationships between physicians and industry (Schneider et al., 2006). Success was modest, with residents more likely to view gifts such as golf and travel to be inappropriate following the workshops (Schneider et al., 2006). Of significant concern was that residents viewed other industry gifts such as industry-sponsored lunches as appropriate (Schneider et al., 2006). These views were consistent with their institution’s policy regarding pharmaceutical detailing (Schneider et al., 2006).

These studies (Keim et al., 1993; Hopper et al., 1997; McCormick et al., 2001; Schneider et al., 2006) highlight the limitations of education as a means to have surgeons process their relationships with manufacturers better and manage their conflicts of interest appropriately. Although insufficient as a sole management strategy, education is both helpful and necessary. The role of education in helping surgeons manage their conflicts of interest could be enhanced by addressing the “hidden curriculum”. Hafferty described the concept of the hidden curriculum in his paper outlining the challenges of successfully incorporating ethics into the medical school curriculum (Hafferty, 1998). Educational initiatives often last only as long as the lecture, as the majority of ethics that is taught and learned in medical school takes place in the hallways rather than the classroom (Hafferty, 1998). Without aligning institutional policies with the ethical curriculum, it will be difficult to make any lasting impact (Hafferty, 1998). The aforementioned research studies (Keim et al., 1993; Hopper et al., 1997; McCormick et al., 2001; Schneider et al., 2006) were performed on residents which may demonstrate the difficulty of employing these educational strategies on already practicing surgeons. Although education of residents may help future surgeons manage their relationships with manufacturers appropriately, it does little to appropriately manage current financial relationships between surgeons and manufacturers.
My examination of the aftermath of the kickback scandals clearly demonstrates that currently, neither manufacturers nor individual surgeons can effectively manage their own conflicts of interest responsibly. Even when facing criminal prosecution, manufacturers reported financial relationships in the most beneficial light (Surgeons for sale, 2008). As required by their deferred prosecution agreement, Zimmer publically disclosed any financial payments from their company to surgeons. However, when determining the cost of flying orthopaedic surgeons in their corporate jet, Zimmer used a rate at least 100 times less than the actual cost of the flight (Surgeons for sale, 2008, p.72). Orthopaedic surgeons have been equally complacent when managing their individual conflicts of interests (Chimonas, Frosch, & Rothman, 2011). Of the 41 orthopedic surgeons who were paid more than $1 million by orthopaedic device manufacturers in 2007, 32 published research articles in 2008. Of these, less than half of the articles disclosed these conflicts of interest despite journal disclosure policies in place (Chimonas et al., 2011).

Physician opinions regarding the appropriateness of financial relationships with industry may not be consistent with their practice. McNeill et al. analyzed surveys that examined gifts given to physicians from industry completed by 823 Australian physicians (McNeill et al., 2006; Macneill et al., 2010). 96% of respondents had accepted food from industry but less than 50% felt that it was appropriate to do so (McNeill et al., 2006; Macneill et al., 2010). Chimonas et al. conducted 6 focus groups exploring physicians’ attitudes towards the relationships between physicians and pharmaceutical company representatives (Chimonas, Brennan, & Rothman, 2003). Chimonas et al. findings suggested that although physicians understand the concept of conflicts of interest, they rationalize their own relationships with industry positively (Chimonas et al., 2003). Physicians were prone to re-interpret data and justify their financial relationships to reinforce their beliefs (Chimonas et al., 2003).

Physician opinions regarding financial relationships with industry are not uniform. Doran et al. used qualitative techniques to examine physician’s attitudes to physician-industry relationships (Doran, Kerridge, McNeill, & Henry, 2006). The authors interviewed 50 Australian physicians and found enormous variability between what physicians found to be appropriate financial relationships with industry (Doran et al., 2006). The results of this research suggest that different physicians manage their conflicts of interests differently. Despite guidelines being in place,
physicians draw on their own comprehension of the risks and benefits of their financial relationships within their broader social context (Doran et al., 2006). To be effective, management strategies need to resonate with the majority of the profession (Doran et al., 2006). These studies illustrate how ineffectual passive guidelines such as medical associations’ codes of ethics (Canadian Medical Association [CMA], 2004; American Medical Association [AMA], 2010) are on physicians, as each physician tends to rationalize their personal financial relationships differently.

Although, it is a necessary requirement to disclose conflicts of interest to research ethics boards prior to research approval, financial relationships that do not involve research participants are left unmonitored. Neither the prohibition of all financial relationships nor leaving individual surgeons to manage their own financial relationships is the solution. An alternative is some degree of mediated oversight. Guidelines have been proposed for managing financial relationships between surgeons and manufacturers at both academic medical centres (i.e. hospitals) and professional organizations (e.g. AAOS) (Camilleri & Parke, 2010; Brennan et al., 2006). Although these guidelines provide methods to appropriately manage type 4 financial relationships between surgeons and manufacturers (through prohibition), I do not believe that they provide methods to manage more nuanced financial relationships (e.g. type 1, 2, and 3 financial relationships) that maximize utility. Rather, using utilitarian calculus may allow oversight committees to maximize utility even when dealing with the most complex and controversial financial relationships. However, in order to allow thorough oversight, financial relationships between surgeons and industry have to be disclosed. But to whom should these relationships be disclosed and who should be entrusted and burdened with this oversight?

2.7 Disclosure of financial relationships with industry

“Transparency is well and good, but accuracy and objectivity are even better. [The profession] does not have to keep confessing its sins. It just has to stop committing them.” (Surowieki, 2002 as quoted in Cain & Detsky, 2008, p. 2895).

The position that disclosure alone can appropriately manage financial relationships between surgeons and industry is faulty. White et al. suggest that with adequate discussion patients are
able to determine whether or not a surgeon’s financial relationship with a manufacturer could negatively impact their care (White, Vaccaro, & Zdeblick, 2007). This position completely fails to account for any of the research in this area. The US quest for transparency makes sense given examples of inappropriate financial relationships between physicians and industry but does little to stop these relationships (Kottow, 2010). This sentiment is echoed by other commentators (Surowieki, 2002; Dana & Lowenstein, 2003; Lichter, 2008; Steinbrook, 2009; McKneally, 2009). In his editorial on the topic of online disclosure, Steinbrook raises the issue that disclosure is an important - but extremely limited - first step as it neither resolves conflicts of interest nor eliminates them (Steinbrook, 2009). Disclosure is a method of informing only, it does not provide a method to manage conflicts of interest. It merely places the burden and responsibility of managing conflicts of interest on the recipient of the information (McKneally, 2009).

The purpose of disclosure to research participants has been summarized by Weinfurt et al. and the same goals are present with respect to disclosure to patients (Weinfurt et al., 2009). It is hoped that disclosure will promote informed decision making, establish or maintain trust, respect the patient’s right to know, minimize legal liability and discourage inappropriate financial relationships (Weinfurt et al., 2009). I am not aware of any empirical evidence that supports the position that disclosure attains these goals. Cain & Detsky raise the additional issue of disclosure causing harm by replacing other more effective strategies to manage conflicts of interest (Cain & Detsky, 2008).

Goodwin and Mullan examined the question of whether or not financial conflicts of interest statements in journal articles impacted the reader’s opinions on the authors and their results (Goodwin & Mullan, 2009). They found that financial conflicts of interest statements that indicated the authors had financial relationships with industry resulted in readers finding the authors less trustworthy (Goodwin & Mullan, 2009). These results are supported by previous research by Chaudhry et al. and Schroter et al. who found that readers felt articles to be of higher quality when the authors were affiliated with an ambulatory care centre rather than with industry (Chaudhry, Schroter, Smith & Morris, 2002; Schroter, Morris, Chaudhry, Smith, & Barratt, 2004). These results (Goodwin & Mullan, 2009; Chaudhry et al., 2002; Schroter et al., 2004) may merely indicate that educated readers of high-level journals are able to account for the
authors’ conflicts of interest. I question whether vulnerable patients would be able to critically evaluate conflicts of interests as successfully as educated readers.

There are certain financial relationships that can never be effectively managed through disclosure. Society would not allow a judge to have a financial relationship with a for-profit prison, regardless of disclosure (Krimsky, 2003). Public trust in the judiciary is too important to be trumped by a judge’s personal interest. In their review article on industry gifts to physicians, Dana & Lowenstein conclude that disclosure can effectively manage conflicts of interests only if patients who are informed can successfully use the information disclosed (Dana & Lowenstein, 2003). Sherlock argued that patients reject the idea of shared-decision making and, rather, approve an entrustment model (Sherlock, 1986). Informed consent used to appease litigators assumes that patients are “autonomous agents capable of defending their interests if only the tools of information and the right of consent are placed at their disposal” (Sherlock, 1986, p. 3). This presumption runs against what we know of sick patients whose anxieties and worries make even the registration of information difficult (Sherlock, 1986). Furthermore, direct disclosure of the consequences and risks of surgery by a surgeon to a patient occurs only after the patient has emotionally committed to surgery (Lidz, Meisel, & Osterweis, 1983).

Like physicians, patients are somewhat self-serving (i.e. invested in their physician) in their views of their physician’s conflicts of interest (Gibbons et al., 1998). Patients are more likely to think that a gift from a pharmaceutical company will influence another individual’s physician more than their own physician (Gibbons et al., 1998). Patients also have a higher threshold for allowing inappropriate gifts from industry to health care professionals than medical specialists do (Macneill et al., 2010). These studies (Gibbons et al., 1998; Macneill et al., 2010) suggest that even if financial relationships are disclosed to patients, patients may not be able to critically evaluate whether these relationships would negatively impact their care.

Jansen & Sumasy argue that information, even though accurate, may distort a patient’s judgement (Jansen & Sumasy, 2003). For example, Sarmiento was approached by an orthopaedic device manufacturer with an offer of $250 000 for the naming rights of a new hip prosthesis (Sarmiento, 2003). If information about that endorsement were disclosed, it may have had the
unintended effect of increasing the patient’s trust in Sarmiento as their surgeon, as the patient may associate endorsement deals with only the most impressive professionals. This might further encourage inappropriate financial relationships between surgeons and surgical device manufacturers. Behaviour economic models have demonstrated this phenomenon (Cain, Loewenstein, & Moore, 2005; Koch & Schmidt, 2010).

Disclosure to patients does seem to increase trust, whether warranted or not, in the profession (Pearson, Kleinman, Rusinak, & Levinson, 2006; Weinfurt et al., 2006). However, trust can be maintained through other mechanisms besides disclosure. Other strategies to manage financial relationships between surgeons and manufacturers, such as mediated oversight, may also serve to increase public trust in the profession. Prohibiting all financial relationships between surgeons and manufacturers may ensure maintenance of public trust in the profession albeit at the expense of beneficial surgeon-manufacturer collaborations. In a survey of vulnerable patients enrolled in cancer research trials, a substantial minority of patients (40%) wanted to know only that oversight mechanisms were established to ensure financial relationships between their physicians and industry were appropriate, rather than have financial relationships disclosed to patients (Hampson et al, 2006). This survey by Hampson et al. suggests that oversight by professional organizations or government agencies may ensure continued public trust without direct patient disclosure.

Disclosure requires strict enforcement to ensure that disclosures are accurate. Even when forced to disclose publically, Zimmer representatives failed to accurately declare the cost of private jet fairs (Surgeons for sale, 2008). Accurate disclosure of conflicts of interest for research articles continues to be woeful, with disclosure rates between less than 50% and 80% (Okike, Kocher, Wei, Mehlman, & Bhandari, 2009; Chimonas et al., 2011). Therefore, unless mandatory legislation for disclosure of financial relationships between surgeons and manufacturers is implemented and strategies for monitoring and enforcement of these disclosures are in place, disclosure will not be comprehensive.

Disclosure alone does not seem to limit inappropriate behaviour. Six U.S. states currently have legislation that enforces disclosure of payments from industry to physicians: Massachusetts,
Vermont, Maine, West Virginia, Minnesota and the District of Columbia (Chimonas, Rozario, & Rothman, 2010). Chimonas et al. examined four years of data following the enactment of mandatory disclosure in Vermont (Chimonas et al., 2010). There has been a dramatic increase in gifts for speaking arrangements and gifts of food (Chimonas et al., 2010). Interestingly, the top 100 recipients (out of 5608 practitioners) received 69% of the total amount of payments (Chimonas et al., 2010).

Ultimately, disclosure’s role in managing financial relationships between surgeons and manufacturers may be limited to allowing thorough oversight and respecting a patient’s right to know. Weinfurt et al. performed 16 focus groups involving 139 patients to explore research participants’ views on conflicts of interest (Weinfurt et al., 2006). They concluded that the goal of promoting informed decision making through disclosure of conflicts of interest is unrealistic (Weinfurt et al., 2006). A more modest and realistic goal for disclosure is the honouring of a research participant’s right to know (Weinfurt et al., 2006). But do patients want disclosure of financial relationships between their orthopaedic surgeons and orthopedic device manufacturers?

2.8 What are patients’ views on financial relationships between surgeons and manufacturers, and do patients want disclosure?

Our present knowledge on patients’ views on financial conflict of interest between orthopaedic surgeons and orthopaedic device manufacturers is limited as there is scant empirical research on the topic. Ovid Medline, Embase and Scopus literature database searches, performed on October 12 2010, using key phrases, “conflict of interest” and “orthopaedic/orthopedic surgery”, yielded fewer than 75 results. Only five articles were empirical in nature, and only one related to my research question (Khan et al., 2007). The remaining articles are opinion pieces and editorials. A review of the broader topic of patient or research participant views on conflicts of interest yields greater returns. However, these broader studies demonstrate considerable variability with regard to population studied and methodology making systematic reviews of findings difficult, although some have tried (Licurse, Barber, Joffe, & Gross, 2010). There are three studies that examine the views of potential research participants (Kim, Millard, Nisbet, Cox, & Caine, 2004; Weinfurt et al., 2006; Weinfurt et al., 2008), three studies that look at views of research participants (Hampson et al., 2006; Grady et al., 2006; Gray, Hlubocky, Ratain, & Daugherty, 2007), five
studies that evaluate the views of the public or potential patients (Mainous, Hueston, & Rich, 1995; Crigger, Courter, Hayes, & Shepherd, 2009; Jastifer & Roberts, 2009; Edwards & Ballantyne, 2009), and only five studies that report on the views of patients (Gibbons et al., 1998; Semin, Güldal, Özçakar, & Mevsim, 2006; Khan et al., 2007; Tattersal, Dimoska, & Gan, 2009; Macneill et al., 2010). Only one research article has investigated patient views in surgical patients (Khan et al., 2007). I will examine these studies in turn, describing their key findings and shortcomings.

Kim et al. used an electronic survey to examine the opinions of 5478 members of the public that were diagnosed with both a chronic illness and who were willing to participate in a clinical trial (Kim et al., 2004). More than 60% of respondents wanted financial relationships of researchers to be disclosed (Kim et al., 2004). This desire for disclosure was correlated to higher levels of respondent education (Kim et al., 2004).

Weinfurt et al. conducted focus groups on potential research participants’ awareness, attitudes and beliefs of researcher’s financial relationships with industry (Weinfurt et al., 2006). Respondents were largely unaware of financial relationships between researchers and industry (Weinfurt et al., 2006). Opinions varied in the respondents’ desire for information regarding conflicts of interest (Weinfurt et al., 2006). The majority of respondents felt that not being told of potential conflicts of interest would negatively affect their trust in the researcher (Weinfurt et al., 2006). However, a significant minority of respondents felt that having potential conflicts of interest disclosed would negatively impact their trust in the researcher (Weinfurt et al., 2006). The researchers found that the riskier the research, the greater the desire for disclosure of conflicts of interest. There may be a difference between patients and research participants in this regard. Research participants often have a choice to decline participation. Patients may have no alternative to a high risk surgery and may be more concerned about the consequences and risks of surgery than their surgeon’s conflicts of interests. Weinfurt et al. found that respondents varied in their ability to understand how conflicts of interest would impact their health (Weinfurt et al., 2006).
Weinfurt et al. surveyed 880 members of the public from a total sample population of 3623 to evaluate potential research participants’ views on conflicts of interest (Weinfurt et al., 2008). 36% of respondents stated that their trust would diminish following disclosure of a researcher’s financial relationships with industry (Weinfurt et al., 2008). However, 59% of respondents stated that their trust would remain unchanged following financial relationship disclosure (Weinfurt et al., 2008). Interestingly, respondents found equity relationships more troubling than per capita payments (Weinfurt et al., 2008). However, this may have been due to the wording of the financial relationships used in the study, with per capita payments described in a far better light than equity payments. Importantly, the researchers found that the presence of financial relationships would not influence respondents’ participation in research trials (Weinfurt et al., 2008). Respondents viewed risk and potential benefits and research trial purpose as far more important issues in their decision making process (Weinfurt et al., 2008).

Perhaps the most valuable research in this area to date is a study conducted by the National Institutes of Health (NIH) and published in the New England Journal of Medicine in 2006 (Hampson et al., 2006). This study examined research participants’ views on financial conflicts of interest in cancer-research trials. It should be noted that although enrolled in research trials, all participants were diagnosed with cancer and were therefore patients too. The research was conducted using 253 face-to-face interviews using a standard questionnaire. The majority of participants (90%) were not worried about financial ties between researchers and pharmaceutical companies (Hampson et al., 2006). As found in other studies, only educational level was correlated with concern of financial relationships between researchers and industry (Kim et al., 2004; Hampson et al., 2006). The higher a participant’s levels of education the more likely they were to be concerned about their researcher’s conflicts of interest. As found in other studies, most participants would still have enrolled in the study even if they had known about such financial conflicts of interest (Weinfurt et al., 2008; Hampson et al., 2006). Only 31% of participants wanted to be informed about their researcher’s financial relationships with pharmaceutical companies but 40% wanted to know that there were oversight systems in place (Hampson et al., 2006).
In 2007, Gray et al. published a study with similar research methods (i.e. survey) and in a similar population (i.e. patients enrolled in cancer research trials) as the NIH study (Gray et al., 2007). In contrast to the NIH study, 52% of patients felt that disclosure of financial relationships was necessary (Gray et al., 2007). This difference may have been due to the differences in the wording of the questions, the techniques of the interviewers or the unique demographic characteristics of each study population. Younger patients were found to be more concerned with conflicts of interest (Gray et al., 2007).

Grady et al. performed a qualitative study with 33 research participants enrolled in clinical trials (Grady et al., 2006). This study specifically examined different types of financial relationships, including royalty payments, equity holdings, consulting agreements, and per capita payments (Grady et al., 2006). The majority of participants wanted information regarding financial relationships between the researcher and industry. Despite wanting this information, participants did not feel that this disclosure would influence their research participation (Grady et al., 2006). These findings support those of other studies (Hampson et al., 2006; Weinfurt et al., 2008). Importantly, participants often rejected the idea of disclosure as they felt it did not help them in the decision whether to participate and they felt it added an extra burden that they would rather not deal with (Grady et al., 2006). Grady et al. raise the point that because many of these participants (like surgical patients) have no other option but to enrol in research trials they “may arguably be the least likely to be in a position to use such information to assess risks associated with financial interests and make decisions accordingly” (Grady et al., 2006). Participants rely on institutional oversight to ensure that financial relationships of the research do not jeopardize their health (Grady et al., 2006).

Mainous et al. surveyed 649 members of the public via telephone and found that only 32% of respondents were aware that physicians could receive personal gifts from pharmaceutical companies (Mainous et al., 1995). 42% of respondents believed that personal gifts increased the cost of their care but only 23% felt that personal gifts decreased the quality of care they received (Mainous et al., 1995). When asked what amount of money physicians should accept from pharmaceutical companies, 33% of respondents surveyed stated that physicians should accept as much as was on offer (Mainous et al., 1995). In terms of demographic variables, only respondent
level of education was significantly related to opinions regarding personal gifts to physicians. Even after controlling for income, residence and knowledge of gifts, respondents with higher levels of education were more likely to regard personal gifts to physicians negatively (Mainous et al., 1995). The results from the survey by Mainous et al. mirror those from other studies regarding impact of respondent’s level of education on views on conflicts of interest (Hampson et al., 2006; Weinfurt et al., 2008; Kim et al., 2004).

Crigger et al. examined opinions regarding gifts from pharmaceutical companies to health care providers by surveying 139 members of the public and comparing their responses to retrospective data provided by 84 family nurse practitioners (Crigger et al., 2009). Members of the public felt that gifts were appropriate only if they were both inexpensive and educational in nature (Crigger et al., 2009). Family nurse practitioners had a greater tolerance for accepting gifts than the general public. Only 25% of the public felt that catered lunch was appropriate, whereas 57% of family nurse practitioners agreed that catered lunches were appropriate to accept. This is in contrast to research by Macneill et al. who found that patients had a greater tolerance for gifts from pharmaceutical companies to physicians than medical specialists did (Macneill et al., 2010).

Edwards and Ballantyne reported results from a survey answered by 151 respondents from a total survey sample of 1524 members of the general public (Edwards & Ballantyne, 2009). 40% of respondents had a high level of awareness of financial relationships between physicians and pharmaceutical companies (Edwards & Ballantyne, 2009). 48% of respondents wanted to be told about relationships between their physicians and pharmaceutical companies (Edwards & Ballantyne, 2009). If given the choice, approximately 40% of respondents would rather be seen by a physician without contact with pharmaceutical representatives (Edwards & Ballantyne, 2009).

Jastifer and Roberts conducted a mail survey of 8936 members of the public, answered by 903 patients (Jastifer & Roberts, 2009). Respondents’ awareness of gifts valued over $50 given by pharmaceutical companies to physicians ranged from 19% to 38.3%, depending on the particular gift asked about. Patient awareness of gifts increased with a patient’s level of education and, independently, the higher a patient’s level of income (Jastifer & Roberts, 2009). As seen in the
study by Crigger et al., patients approved of gifts if they were either inexpensive (e.g. ballpoint pen) or related to patient care (e.g. medical book) (Jastifer & Roberts, 2009). Patients disapproved of meals, golf tournaments and travel allowances (Jastifer & Roberts, 2009). The higher a patient’s level of education and, independently, the higher a patient’s level of income the more likely a patient was to believe that gifts increase the cost of medical care (Jastifer & Roberts, 2009).

Gibbons et al. randomly surveyed 196 patients at a military and civilian tertiary care center and compared their views with 268 physicians at the centers (Gibbons et al., 1998). They found that 54% of the patients were aware that gifts were given to physicians by pharmaceutical companies. There was no obvious difference between physicians’ and patients’ opinions on the appropriateness of gifts (Gibbons et al., 1998). Interestingly, patients who thought that their physician accepted gifts from pharmaceutical companies found accepting gifts more appropriate than patients who did not think their physician accepted gifts (Gibbons et al, 1998).

Turkish investigators, Semin et al., examined the issue of pharmaceutical promotion in their country through 584 patient self-administered questionnaires (Semin et al., 2006). Higher levels of education were correlated with awareness of financial relationships between pharmaceutical companies and physicians (Semin et al., 2006).

Tattersal et al. surveyed 906 patients at family physician offices in Australia (Tattersal et al., 2009). 24% of patients were aware of financial relationships between their family physician and pharmaceutical companies (Tattersal et al., 2009). More than 80% of patients felt that knowing about financial relationships between their physician and pharmaceutical companies would be important (Tattersal et al., 2009).

Macneill et al. compared patient views on the appropriateness of different gifts given by pharmaceutical companies to physicians with those of physicians (Macneill et al., 2010). 832 (2253 mailed) physicians and 757 (3000 mailed) patients returned surveys. They found that in 18 out of 20 types of gifts asked about, patients had a higher threshold for finding gifts from pharmaceutical companies to physicians acceptable than medical specialists did (Macneill et al., 2010). These results are in contrast to those found by other studies (Crigger et al., 2009; Gibbons
et al., 1998). This may be due to different study methodology, different study settings and locations, or different knowledge regarding conflicts of interest held by the public and health care professionals surveyed. Importantly though, neither medical specialists nor members of the public were supportive of any gifts that were not aimed clearly at improving medical care.

2.9 Should we generalize previous studies of other populations to surgical patients?

It may be inappropriate to systematically review and generalize the findings of the previous surveys exploring respondents’ awareness and concerns about financial relationships between researchers or health care providers and industry, although some have done so (Licurse et al., 2010). Many of these studies (i.e. in Section 2.8) explored different concepts, used different methods and surveyed different populations. Findings from surveys of the general public or potential research participants may not be generalizable to surgical patients. Unlike the general public or potential research participants, surgical patients are more vulnerable. The knowledge differential about surgery between even the most educated patient and their surgeon is enormous. The decision to treat is at the surgeon’s discretion and during surgery the patient has no ability to monitor the performance of the surgeon. This speaks to the significant difference between a patient facing surgery and a patient being evaluated for hypertension. I content that unlike many potential research participants or members of the general public, surgical patients may have limited treatment options and their choices may be further restricted by social, geographical and insurance limitations.

Similarly, views of primary care patients may not be generalizable to patients facing surgery. Of the studies reviewed, the views of patients with cancer enrolled in research trials may most closely resemble those of surgical patients. However, the patients in the study by Hampson et al., for example, were possibly overwhelmed by life-threatening illness and this may have influenced their judgment with regard to how they perceived financial conflicts of interest (Hampson et al., 2006). As suggested in Nabel’s corresponding editorial, the results from the study by Hampson et al. may be unique to patients facing an uncertain future and may not be representative of patient opinions in other fields of medicine (Nabel, 2006).
Despite the difficulties of generalizing results of the studies reviewed to surgical patients, important concepts emerge. Patients may have a higher threshold for finding financial relationships appropriate (Macneill et al., 2010). Disclosure, without oversight, as an approach to prevent inappropriate financial relationships may prove to be no more effective in deterring inappropriate financial relationships than doing nothing at all. Moreover, vulnerable patients may feel burdened by disclosure of financial relationships (Grady et al., 2006). Drawing from these conclusions, surgeons may actually harm their patients by disclosing their financial relationships with manufacturers, by increasing their anxiety and taking focus away from more important consequences and risks of surgery discussed during informed consent, without preventing inappropriate financial relationships.

The only published study looking at surgical patients was a self-administered eight-question patient survey examining the opinions of 245 patients (Khan et al., 2007). Pre-operative, post-operative and non-operative patients were included (Khan et al., 2007). 94.3% of patients felt that it was to the patient’s benefit “if doctors can advise the medical device manufacturers to improve/design medical instrumentation” (Khan et al., 2007). 66.5% of patients felt that it was appropriate for doctors to be compensated for this advisory role (Khan et al., 2007). 72.7% of patients wanted financial relationships with companies, whose products would be involved in their care, to be disclosed (Khan et al., 2007). Patients with a higher level of education were more perturbed by the financial relationship between surgeons’ and manufacturers (Khan et al., 2007).

The results from the survey by Khan et al. are suggestive of patient support of financial relationships between surgeons and manufacturers but by no means definitive given methodological concerns regarding the leading nature of the questions, the limited types of financial relationships evaluated, and the grouping together of all patients regardless of surgical treatment. Importantly, Khan et al. did not address the difficult ethical dilemmas the orthopaedic surgery field is currently facing. It only addressed the issue of whether or not surgeons should be fairly reimbursed for designing particular surgical implants. It did not examine how patients feel about payments to surgeons from manufacturers for using particular implants, luxury vacations for continuing medical education, or excessive consulting fees for questionable work. Nor did it
examine patient views on the method of disclosure. Patient views on disclosure as a method of managing financial relationships between surgeons and manufacturers is of particular importance in light of the Physician Payment Sunshine Provision which mandates disclosure on a publically searchable website (PPAC, 2010). The only study on the subject of internet use in elderly patients with arthritis found only approximately 25% had internet access at home making online disclosure even less effective as a management strategy (Tak & Hong, 2005).

Surgeons are reluctant to fully disclose financial conflicts of interest even when mandated to do so (Okike et al., 2009; Chimonas et al., 2011). Concerns about potential disruption of the surgeon-patient relationship due to disclosure of financial relationships between surgeons and manufacturers may be allayed with more complete knowledge of what orthopaedic surgery patients know, want to know, and how, if at all, they want to be informed about financial conflicts of interest.

2.10 How does patient trust in their surgeon influence desire for disclosure?

Patients need the help of physicians to fulfill necessary human needs (Pellegrino & Thomasma, 1993). Physicians help maintain or restore health and help prevent or palliate death (Pellegrino & Thomasma, 1993). It is impossible to separate the patient-physician relationship from trust (Pellegrino & Thomasma, 1993). This “ineradicability of trust” from the patient-physician relationship is a major focus of the ethics of the medical profession (Pellegrino & Thomasma, 1993). Trust in the medical profession influences patients’ desires to participate in research (Corbie-Smith, Thomas, Williams, & Moody-Ayers, 1999) and their adherence to treatment (Safran et al., 1998). It has also been suggested that unhealthy behaviours are decreased in patients who trust their physicians as these patients are more likely to seek medical care and follow medical advice (Fiscella, Franks, Clancy, Doescher, & Banthin, 1999).

The superior knowledge and power possessed by a physician predetermines the inequality of this relationship. But without vulnerability, there is little need for trust (Hall, Dugan, Zheng, & Mishra, 2001). The greater the vulnerability of the patient, the greater the trust placed in the healthcare provider (Hall et al., 2001). This is clearly demonstrated in the patient-surgeon
relationship. The anesthetized patient undergoing surgery is unable to monitor their surgeon’s performance. The consequences of surgery are often irreversible. The pain or suffering prior to surgery and the consequences of delaying surgery may prohibit patients from obtaining second opinions particularly when faced with rapidly progressive disease or lengthy waiting period. These factors all add to the surgical patient’s vulnerability and increase the patient’s necessary trust in their surgeon. The patient relies on the surgeon’s competence and willingness to heal, rather than to exploit the patient undergoing surgery for personal profit or prestige (Baier, 1986).

Ende et al. surveyed 312 patients in a primary care setting to examine their desire to make medical decisions (Ende, Kazis, Ash, & Moskowitz, 1989). Patients preferred to have their medical decisions made by their physician but did want to be informed (Ende et al., 1989). The majority of patients wanted a greater role in the decision making process when faced with a less severe illness (e.g. upper respiratory infection) than when faced with a severe illness (e.g. myocardial infarction) (Ende et al., 1989). The demographic variables that correlated with an increased desire to have a greater role in the decision making process were younger age, higher level of education and higher level of income (Ende et al., 1989).

Arora et al analyzed 2147 surveys completed by patients from the Medical Outcome Study to examine patients’ desire for informed consent (Arora & McHorney, 2000). The Medical Outcome Study was a cross-sectional health related survey that was conducted in Boston, Los Angeles and Chicago from 1986-1990. 69% of respondents preferred to leave their medical decisions to their physicians (Arora & McHorney, 2000). The higher a respondent’s level of education and the younger a respondent, the more likely a respondent wanted to have an active role in the decision making process (Arora & McHorney, 2000).

McKneally and Martin performed a qualitative study of 36 post-esophagectomy patients (McKneally & Martin, 2000). Their findings indicated that when consenting to surgery, patients valued the expertise of the surgeon rather than medical information provided during the consent process (McKneally & Martin, 2000). More specifically, “patients accepted expert recommendation as [reason to] consent to treatment” (McKneally and Martin, 2000, p. 268).
McKneally et al. replicated their previous study in patients consenting to cholecystectomy, a surgery with far less risks and far better prognosis than esophagectomy (McKneally, Ignagni, Martin, & D’Cruz, 2004). In contrast to the uniform views of the esophagectomy patients, the cholecystectomy patients had a more varied attitude toward informed consent, ranging from entrustment to that of an educated consumer (McKneally et al., 2004). These results reinforce the importance of context when examining patient attitudes and belief. Generalizing findings from one population to another may be inaccurate.

Importantly, trust generates beliefs that are extremely resistant to evidence (Jones, 1996). In their patient survey, Gibbons et al. found that patients who thought their physician received gifts from industry felt that receiving gifts was more appropriate than patients who thought their physician refused gifts (Gibbons et al., 1998).

Maintaining trust and building trustworthiness in the surgical profession maximizes utility (Rhodes & Strain, 2000). As such, the surgical profession has the maintenance and promotion of trust as a primary focus of their professional ethic (Pellegrino & Thomasma, 1993). Today’s surgeons have benefited from the history of trustworthy surgeons who protected, rather than exploited, the vulnerabilities of their patients (Rhodes & Strain, 2000). Today’s surgeons have a responsibility to uphold the trustworthiness of the profession so that the next generation of patients has the necessary trust in the next generation of surgeons (Rhodes and Strain, 2000).

2.11 Research rationale

Possible unethical behaviour by surgeons in their relationship with manufacturers has significant implications. Allegations of kickbacks given to surgeons by manufacturers erode the trustworthiness of the profession and undermine the trust patients have in their surgeons. Trust is an essential feature of the patient-surgeon relationships. In order to maximize utility, the maintenance and promotion of trust is an obligation of the surgical profession (Cooney, 2007; Pellegrino & Thomasma, 1993). If the surgical profession is to maintain patient trust, patient views and opinions need to be explored and taken into account in any future recommendations on methods of managing financial relationships between surgeons and manufacturers.
I hypothesize that patients view those financial relationships between surgeons and manufacturers that have the potential to benefit current or future patients (e.g. consulting agreements) as appropriate and that patients view those financial relationships that do not clearly benefit current or future patients (e.g. gifts) as inappropriate. Moreover, I hypothesize that patients do not want direct and full financial disclosure from their surgeon and that patients want the responsibility of regulation of these financial relationships entrusted to higher levels of oversight (i.e. professional organizations). This research project provides insight into patients’ current knowledge of the relationship between surgeons and manufacturers, and how patients view surgeon-manufacturer ties. The results will provide empirical evidence that may be used in utilitarian calculus to maximize utility when managing financial relationships between surgeons and manufacturers.
3 Qualitative methods

3.1 Design

The qualitative study used qualitative description to discover patient-derived concepts and themes regarding financial relationships between surgeons and surgical device manufacturers (Sandelowski, 2000). Research questions that evaluate patient opinions and attitudes are perfectly suited to qualitative description (Sandelowski, 2000). Qualitative description can incorporate methods from other approaches such as the inductive and iterative interview methods of grounded theory (Sandelowski, 2000). It provides insight into complex phenomena without adding further complexity by developing a theory (Milne & Moore, 2005).

3.2 Sample

Male and female patients were recruited from two surgeons’ arthroplasty follow-up clinics at Mount Sinai Hospital in Toronto, Ontario. Mount Sinai Hospital is a tertiary care centre within a medical system that has a single provincially-run medical insurer. These two surgeons’ clinics were chosen as they treat a broad spectrum of patients including patients requiring complex revision arthroplasty as well as young adults requiring arthroplasty. Patients were initially randomly recruited but purposive recruiting began once concepts and themes emerged from data analysis. Purposive sampling allows researchers to uncover unique themes across a heterogeneous patient population with a variety of hip pathologies treated with arthroplasty (e.g. post trauma, OA, AVN, DDH, revision, inflammatory arthritis) (Sandelowski, 1995). Patients met inclusion criteria if they were at least 3 months from either primary or revision hip or knee joint replacement surgery, were between 18-90 years old, could adequately communicate in English and were able to provide informed consent. Patients were excluded if they failed to meet inclusion criteria or were felt to be too psychologically fragile to participate. The attending surgeon established first contact with eligible patients to determine whether or not patients were willing to participate in the research study. If the patient was willing to participate, I met with the patient to discuss the study, answer any questions and ultimately obtain informed consent. I informed patients that participation was voluntary and that their current or future care would not be affected by participation or withdrawal. I informed patients that their interviews were
confidential, identifying data would not appear on the transcripts and that their surgeon would not have access to their interview audiotapes or transcriptions. This information was provided to encourage open and honest interviews. A copy of the consent form can be found in Appendix 1. Patients were recruited over a period of 3 months from January to March 2010.

Interviews were conducted until “saturation” was reached, a term describing a theoretical point beyond which no new concepts arise as a result of further interviews. In the only quantitative article on saturation, Guest et al. determined that their codebook would have been complete and stable following 12 interviews (Guest, Bunce, & Johnson, 2006). However, the authors did caution that non-homogeneous groups may require greater interviews to obtain saturation. Due to the heterogeneous study population, 33 interviews were conducted before I reached theoretical saturation. I conducted a similar number of interviews to previous qualitative studies done with surgical patients (McKneally & Martin, 2000; McKneally et al, 2004).

3.3 Ethical considerations

The study was approved by the Research Ethics Board at Mount Sinai Hospital. Informed consent was obtained from each participant. Interview transcripts were rendered anonymous and kept in secure storage to ensure confidentiality. Patients were reimbursed $10 for parking. There were otherwise no clinical or material incentives for participation. There was no external funding source for this investigation.

3.4 Data Collection

Unlike other schools of qualitative research, qualitative description begins with a literature review on which to base the research and structure the interview (Thorne et al., 1987). An interview guide (Appendix 2) was developed based on an extensive literature review. Using the interview guide, I conducted semi-structured interviews in a private interview room in the orthopaedic clinic following a patient’s clinic visit. Interviews lasted between 20 to 45 minutes. As the only interviewer, I was able to ensure consistency in interview technique and data collection. Moreover, as I had performed the literature review and was performing the data analysis, I was in a good position to explore and probe patient-derived themes and concepts.
The interview guide was iteratively altered based on patient-derived concepts and themes brought out in previous interviews (Britten, 1995). Interviews were audio-taped and demographic information was collected from each participant (Appendix 3). All interviews were transcribed verbatim by a professional transcriptionist. I listened to each interview while reviewing the interview transcript to ensure accuracy and completeness. I made corrections and added notations, emphasis and punctuation as required. Transcriptions were imported into MAXQDA 10 software (Udo Kuckartz, Berlin). MAXQDA allows for electronic coding and electronic memos as well as the ability to link codes and collapse codes into categories and themes accurately and easily. Qualitative analysis software does not perform any of the analysis on behalf of the researcher but does assist in the organization of the analysis. It also provides an electronic data and decision trail that increases rigor via auditability (Beck, 1993).

3.5 Data Analysis

Data were analyzed using qualitative content analysis throughout data collection (Sandelowski, 2000). The interview guide was altered as needed to explore themes that emerged from analysis. Before analysis of each interview, I immersed myself in the data by listening to the entire interview to try to determine the patient’s tone and meaning. Data analysis centers on coding data into categories for the purpose of comparison. In coding, data was analyzed by breaking down data into small units or codes representing certain concepts or content derived from the data (Milne & Moore, 2005). Codes were defined, linked with other related codes and then applied systematically across previously analyzed data. I filed any thoughts or considerations with regards to an individual code as a memo. Memos were used to record my thought process and synthesis of the patient-derived codes. For example, under the code “vulnerability of patient to change surgeons”, participants described “pain and inability to promptly change surgeons may make patients continue with a surgeon even if they feel uncomfortable with the surgeon's relationships with orthopaedic device manufacturers.” Examples of codes, definitions and memos are provided in table 1. Ultimately, 87 distinct codes were derived from the data. Throughout coding I had frequent discussions with my supervisors and senior qualitative researchers to ensure accuracy of analysis.
As analysis proceeded, I grouped similar codes together as categories. Categories were labelled by what the codes within a category had in common. For example, the category “concerns regarding disclosure” contained the codes “too much information overwhelming patients” and “vulnerability of patient to change surgeons”. Examples of categories are provided in table 2. The data was synthesized into 28 categories.

Finally, I grouped associated categories into identifiable overarching themes. Themes described broad concepts that ran throughout the majority of the interviews. An example of a theme is provided in table 2. Once data was analyzed and interpreted, it was clear that our sample size was sufficient since saturation appeared to have been reached, and no new themes emerged from further analysis.

3.5.1 Rigor

In an effort to increase research rigor, Mays and Pape describe two goals for the qualitative researcher (Mays and Pape, 1995). Firstly, the researcher should report their methods and analysis so that another researcher could repeat the analysis on the data and draw the same conclusions (Mays and Pape, 1995). Secondly, following analysis, the researcher’s description of the phenomenon should be both plausible and coherent (Mays and Pape, 1995). Beck calls for credibility, fittingness and audibility in evaluate the rigor of qualitative research (Beck, 1993). Credibility refers to how true to the phenomenon the findings of the research are (Beck, 1993). Fittingness pertains to the generalizability of a study’s conclusions (Beck, 1993). Audibility refers to how a researcher’s decisions can be tracked and supported throughout the research process (Beck, 1993).

3.5.2 Credibility

Credibility refers to the reliability of a qualitative study’s findings (Beck, 1993). Although I used an interview guide, I allowed patients to determine the flow of the interview and probed patient responses and explored themes with non-directive open ended questions. I began the interview by informing patients that they could speak honestly, that there were no incorrect answers and that we merely wanted to learn their opinions regarding the relationships between surgeons and manufacturers (Appendix 2). Whenever I provided information to a patient, I
ensured that information was framed without bias (Appendix 3). Although the interview guide was based on an extensive literature review, it was altered as concepts and themes emerged from analysis. To further establish credibility, I checked my understanding of a patient’s response by clarifying any uncertainty during the interview and summarizing emerging concepts during the interview rather than relying on my own assumptions.

Beck proposes that researchers should validate their findings with the participants (Beck, 1993). This is a technique used in other qualitative research (McKneally & Martin, 2000; McKneally et al., 2004). However, Sandelowski argues against post-hoc member checking because the goals of the participant and researcher may conflict (Sandelowski, 1993). The researcher is left with little guidance if a patient disagrees, retracts a statement or forgets how they felt at the time of the interview or the content of the interview (Sandelowski, 1993). I therefore refrained from post-hoc member checking.

I defined all codes to ensure accuracy and reproducibility of my data analysis. My coding system and data analysis was reviewed by my research supervisors and experienced qualitative researchers to prevent bias.

3.5.3 Fittingness

Fittingness pertains to a study’s findings in relation to the established literature and the meaning the conclusions will have on others (Chiovetti & Piran, 2003). I reviewed my conclusions with my program advisory committee, experts in biomedical ethics and orthopaedic surgeons who felt my conclusions represent a fitting analysis of patient views on the financial relationships between surgeons and manufacturers. As described in the subsequent sections, my conclusions are supported by previous studies in this field. Importantly, through purposive sampling I was able to obtain opinions from the range of patients that require joint replacements further enhancing the fittingness of the results.
<table>
<thead>
<tr>
<th>Code</th>
<th>Definition, Related Codes and Memos</th>
</tr>
</thead>
<tbody>
<tr>
<td>Too much information overwhelming patients</td>
<td>Patient feels that disclosure may be too much information to process and may be overwhelming and therefore take away from other important aspects of the consent. &lt;br&gt; <strong>Relates to other codes:</strong> Pain and disability; patient too concerned with pain to deal with other issues</td>
</tr>
<tr>
<td>Vulnerability of patient to change surgeons</td>
<td>Concern that due to vulnerability of patient, unwilling to change surgeons but patient feels uneasy about particular financial relationships between surgeon and manufacturers  &lt;br&gt; <strong>Relates to other codes:</strong> Pain and disability; patient too concerned with pain to deal with other issues; not major enough concern to change surgeons  &lt;br&gt; <strong>Memo</strong> Pain and inability to promptly change surgeons may make patients continue with a surgeon even if they feel uncomfortable with the surgeon's relationships with orthopaedic device manufacturers. The idea that patients do not have the ability to change the actions of their surgeon.</td>
</tr>
<tr>
<td>No difference between health care and any other industry</td>
<td>Patient has no problem with incentives and sees no difference between practices in other industries.  &lt;br&gt; <strong>Related to codes:</strong> Surgeon's business outside the immediate surgeon-patient relationship is not patient’s business  &lt;br&gt; <strong>Memo</strong> Do these patients entrust their surgeon to make the right choice or are they buyer-beware information seekers? Are patients demanding their surgeons to use Virtue ethics?</td>
</tr>
<tr>
<td>Support for reimbursement for expertise</td>
<td><strong>Definition:</strong> Patient feels that it is appropriate for surgeons to be reimbursed for their expertise.  &lt;br&gt; <strong>Related to codes:</strong> Support for surgeon-manufacturer financial relationship; positive view on surgeon-manufacturer relationships</td>
</tr>
</tbody>
</table>
Table 2. Examples of categories and themes developed in Qualitative Study

<table>
<thead>
<tr>
<th>Category</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concerns regarding disclosure</td>
<td>Patient raises concerns about the idea of disclosure as a means to mitigate potential harms brought about by financial relationships between orthopaedic surgeons and orthopaedic device manufacturers.</td>
</tr>
<tr>
<td>Support for surgeon-manufacturer</td>
<td>Patients imply that they feel financial-relationships between surgeons and manufacturers is beneficial.</td>
</tr>
<tr>
<td></td>
<td>relationships</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Theme</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disclosure of financial relationships</td>
<td>Patients' ideas of disclosure as a means of mitigating damage from conflicts of interest</td>
</tr>
<tr>
<td>may shift focus away from more important risks during the consent process</td>
<td></td>
</tr>
</tbody>
</table>

3.5.4 Auditability

My interviews were audio taped and transcribed verbatim. All of my decisions and thought processes are easily followed with the use of code definitions and memos in MAXQDA 10. My codes were reviewed by two experienced qualitative researchers to ensure that my decision trail was appropriate.
4 Qualitative Results

4.1 Patient Demographics

33 patients were interviewed in a three month period between January and March 2010 (Table 3).

4.2 Qualitative Description

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

1. Many patients are unaware of the existence of financial relationships between surgeons and surgical device manufacturers. Despite the publicity in the lay media (Abelson, 2006; Abelson, 2009; Feder, 2007; Feder, 2008; Harris, 2009; Kelly 2009) regarding financial relationships between orthopaedic surgeons and manufacturers, the vast majority of patients interviewed were unaware that these relationships existed:

   “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 manufacturers:

   “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.”

2. 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 in the improvement and innovation of surgical devices as surgeons have unique intra-operative experience that may yield improvements in surgical device design:

   “As Plato said, ‘if you are making flutes, you’d better talk to the flutist’.”

Regarding relationships with manufacturers that involve educating other health care providers about a company’s product, patients felt that this too was a positive relationship.
Table 3. Patient demographic data in Qualitative Study

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Number of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
</tr>
<tr>
<td>18-39</td>
<td>1</td>
</tr>
<tr>
<td>40-49</td>
<td>3</td>
</tr>
<tr>
<td>50-59</td>
<td>8</td>
</tr>
<tr>
<td>60-69</td>
<td>12</td>
</tr>
<tr>
<td>70-79</td>
<td>7</td>
</tr>
<tr>
<td>&gt;79</td>
<td>2</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>17</td>
</tr>
<tr>
<td>Male</td>
<td>16</td>
</tr>
<tr>
<td><strong>Employment Status</strong></td>
<td></td>
</tr>
<tr>
<td>Working</td>
<td>12</td>
</tr>
<tr>
<td>Temporarily off work</td>
<td>3</td>
</tr>
<tr>
<td>Retired</td>
<td>17</td>
</tr>
<tr>
<td><strong>Marital Status</strong></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>3</td>
</tr>
<tr>
<td>Married</td>
<td>24</td>
</tr>
<tr>
<td>Divorced</td>
<td>2</td>
</tr>
<tr>
<td>Widowed</td>
<td>4</td>
</tr>
<tr>
<td><strong>Educational Level</strong></td>
<td></td>
</tr>
<tr>
<td>Some High School</td>
<td>1</td>
</tr>
<tr>
<td>High School</td>
<td>3</td>
</tr>
<tr>
<td>Some College/University</td>
<td>8</td>
</tr>
<tr>
<td>University</td>
<td>12</td>
</tr>
<tr>
<td>Graduate/Professional School</td>
<td>9</td>
</tr>
<tr>
<td><strong>Time since surgery</strong></td>
<td></td>
</tr>
<tr>
<td>3-6 months</td>
<td>3</td>
</tr>
<tr>
<td>7-12 months</td>
<td>8</td>
</tr>
<tr>
<td>13-24 months</td>
<td>4</td>
</tr>
<tr>
<td>25-60 months</td>
<td>7</td>
</tr>
<tr>
<td>61-96 months</td>
<td>2</td>
</tr>
<tr>
<td>More than 97 months</td>
<td>9</td>
</tr>
</tbody>
</table>
“If that surgeon is helping to teach other surgeons how to use it properly, it’s ... a good positive thing, and not a problem.”

When contemplating whether or not a particular type of relationship was appropriate, 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 the majority of patients felt that it is appropriate for surgeons to be reimbursed for their expertise, patients were more discerning when considering relationships that involved kickbacks. 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 patients interviewed judged kickbacks to be inappropriate:

“You know, if it is just being just used as a profit thing and a kick-back to the surgeon, then I wouldn’t agree.”

Patients were particularly concerned about the prospect of receiving an inferior product because of an incentive-based relationship 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 gone with who’s spoiling me.”

3. Disclosure of financial relationships may shift focus away from more important consequences and risks of surgery during the consent process. The majority of patients do
not view disclosure of financial relationships to patients as beneficial. Most patients felt that
disclosure would take away focus from other more important pre-operative issues:

“I don’t think we are knowledgeable enough to know whether it matters, you’d 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.”

Moreover, patients felt that too much information pre-operatively 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.”

Many patients interviewed felt that a surgeon’s business with a device manufacturer should not
involve the patient as it would not influence their decision making prior to surgery:

“It is useless information for me, it’s not going to help my decision whether to have
surgery or not. It’s not going to make any difference in my surgery.”

Furthermore, many patients felt that they would have difficulty understanding the complexities
of financial relationships between surgeons and manufacturers:

“You are into areas where people don’t have enough intrinsic training in the field to make
use of that information.”

However, views on disclosure may be different for young patients. Unlike older patients who
may outlive their joint replacement, younger patients face a future of multiple revision surgeries.
These patients may want greater ownership of decisions surrounding their surgery, including the
choice of surgical device:

“So, for an older person, I think that it wouldn’t matter as much, because that will
hopefully be the only hip replacement that they are going to need for the rest of their
life….I am going to need replacements for the rest of my life and I want like the top of the
line, so that … that’s the difference between… could be the difference between me needing
surgery, you know, fifteen years from now, or 25 years from now. And I will be at a stage in my life where that’s huge, you know, I could be a young mother.”

4. **Patients support oversight at the professional level but reject the idea of government involvement in oversight.** Although patients disapproved of disclosure to patients as a method to manage financial relationships between surgeons and manufacturers, 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-manufacturer relationships]. The [Professional Regulatory Body] should be the ones that intervene.”

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

   “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 remuneration in any way for anything, including gifts.”

Interestingly, despite interviewing patients within a medical system that has a single provincially-run medical insurer, the vast majority of patients were against government oversight of financial relationships between surgeons and manufacturers:

   “I think the government should just stay out of this as much as possible.”

5. **Patients’ entrust their surgeon to make appropriate patient-centered choices.** Ultimately, patients want decisions regarding the appropriateness of financial relationships with manufacturers to be made by their surgeon. Importantly, patients expect surgeons to make these decisions whilst holding the patient’s 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 or not, most patients felt that they had little other choice other than to
implicitly trust that their surgeon would place the patient’s interests above the financial interests of the surgeon:

“But the truth of the matter is … you have to have faith in the person when they cut you open.”
5 Qualitative Discussion

This qualitative study explores patient views on the financial relationships between orthopaedic surgeons and orthopaedic device manufacturers. Given the present focus on conflicts of interest in orthopaedic surgery, the results of this study provide much needed patient insight and input into how surgeons should manage their relationships with manufacturers.

The finding that patients are largely unaware of the financial relationships between orthopaedic surgeons and device manufacturers is new. To my knowledge, no previous published research has asked or answered this question. Although patients are largely unaware of relationships between surgeons and manufacturers, more than half of the patients interviewed were aware of financial relationships between physicians and the pharmaceutical industry. Two reasons for this phenomenon are worth mentioning. The majority of interactions between device manufacturer detailers and surgeons do not occur in the vicinity of the conscious patient. However, interactions between pharmaceutical company detailers and physicians can be noticed by patients (e.g. promotional materials in office and pharmaceutical samples) in a doctor’s office. There has also been a greater emphasis in the lay media on pharmaceutical company’s indiscretions than those of surgical device manufacturers.

Patients support relationships with manufacturers that provide potential benefit to current or future patients. The patients interviewed in this study do not paint all relationships between surgeons and manufacturers with the same brush. They view relationships in which a surgeon’s knowledge and experience is required for product innovation and education differently to relationships which offer no potential benefit current or future patients. Patients acknowledge that surgeon input is vital in the discovery of new and improvement of current surgical treatments. They support surgeons being utilized and reimbursed by device manufacturers for a surgeon’s expertise. These findings are consistent with quantitative research examining patient views on surgeons as manufacturer consultants (Khan et al., 2007) and physician-industry relationships (Jastifer & Roberts, 2009; Crigger et al., 2010; Macneill et al, 2010).

Patients interviewed felt that financial relationships were difficult to comprehend and they would prefer to concentrate on the important consequences and risks of surgery rather than on the more
abstract risk of their surgeon’s conflicts of interest. As Weinfurt et al. found in their 2008 study, conflicts of interest are placed much lower on patients decision making priority lists (Weinfurt et al., 2008). My findings are in contrast to the results of a review of previously conducted quantitative studies that reported a strong patient desire for disclosure (Licurse et al., 2010). However, this review included studies that did not examine vulnerable patients facing surgery with major surgical risks and consequences as a significant component of their decision making process. In fact, most of the studies in the review used potential patients, potential research participants or members of the general public, who arguably have fewer if any competing worries, than do surgical patients. Patients interviewed in my study had an outlook similar to those more vulnerable research participants surveyed in cancer research trials (Hampson et al, 2006; Grady et al., 2006). Vulnerable research participants often rejected the idea of disclosure as they felt it did not help them in the decision to participate and they felt it added an extra burden that they would rather not deal with (Grady et al., 2006). The patients interviewed in this qualitative study endorsed this view. Like research participants in cancer trials, surgical patients have limited options and therefore they “may arguably be the least likely to be in a position to use such information to assess risks associated with financial interests and make decisions accordingly” (Grady et al., 2006). Additionally, in certain regions, lengthy wait times limit patient options and further decrease the benefit a patient may receive from disclosure of a surgeon’s conflicts of interest. A patient may be forced to persist with a surgeon despite being uncomfortable with their surgeon’s relationship with manufacturers because the waiting list to see an alternate surgeon will result in prolonged pain and suffering. My qualitative study, supported by surveys of cancer research trial participants, demonstrates that vulnerable patients have less desire for disclosure than the general public or patients in a primary care practice.

The Physician Payment Sunshine Provision will ensure that all significant financial relationships between U.S. surgeons and manufacturers will be available on publically-searchable websites by September 30th 2013 (PPAC, 2010). To my knowledge, no other country has passed similar legislation. Although a public website has the potential to inform patients about a surgeon’s financial relationships with manufacturers, it is unclear how this website will actually benefit patients. It is unknown how many patients will visit the website. Tak & Hong studied the use of the internet in patients over 60 with arthritis and found that only a quarter of them had access to
the internet and only 13% used the internet to research arthritis. It is doubtful that a greater proportion would use the internet to search their surgeon’s relationships with manufacturers (Tak & Hong, 2005). Although, publicly searchable websites resulting from the Physician Payment Sunshine Provision will provide a form of transparency it will not allow a surgeon to add any information that the surgeon may feel justifies the disclosed relationship and is necessary to promote an informed decision by the patient. Ironically, it is quite plausible that a public website will merely increase the desirability of surgeons with industry relationships of substantial worth. Without appropriate education and information, patients may view industry relationships similar to endorsements of professional athletes. Weinfurt et al. performed 16 focused groups involving 139 patients to explore research participants’ views on conflicts of interest (Weinfurt et al., 2006). They concluded that the goal of promoting informed decision making through disclosure of conflicts of interest is unrealistic (Weinfurt et al., 2006). It is unlikely that disclosure alone will help manage surgeon’s financial relationships with manufacturers appropriately.

Strict legislation and enforcement is required for disclosure to be accurate. Even when forced to disclose publically, Zimmer representatives failed to accurately declare the cost of private jet fares (Surgeons for sale: Conflicts and Consultant Payments in the Medical Device Industry, 2008). Accurate disclosure for research articles continues to be woeful, with disclosure rates between less than 50% and 80% (Okike et al., 2009; Chimonas et al., 2011). Therefore, unless mandatory legislation is implemented, disclosure will not be comprehensive. However, without thorough review of disclosed relationships, disclosure does not seem to significantly influence behaviour. Six states currently have legislation that enforces disclosure of payments from industry to physicians: Massachusetts, Vermont, Maine, West Virginia, Minnesota and the District of Columbia (Chimonas et al., 2010). Chimonas et al. examined 4 years of data following the enactment of mandatory disclosure in Vermont (Chimonas et al., 2010). Over the four years of study, there has been a dramatic increase in gifts for speaking arrangements and gifts of food (Chimonas et al., 2010).

In my study, patients supported oversight of financial relationships between surgeons and manufacturers. However, patients rejected the idea of further government involvement in oversight. This result is surprising as the study was performed within a socialized health care
system. Rather than further government intervention, patients felt that oversight should be at the level of the hospital or professional organizations. Outside of the US, where information regarding surgeon-manufacturer relationships will be publically available by 2013, this will require legislation to mandate disclosure of financial relationships to either the hospital or professional bodies. Importantly, the data suggests that patients do feel that professional self-regulation is appropriate and that, despite recent scandals, our profession can be trusted with the management of our member’s conflicts of interests. Oversight by the profession would be more comprehensive than hospital oversight as many surgeons work in surgeon-owned hospitals and clinics, making impartial oversight difficult. Moreover, hospitals may be in a conflict of interest, particularly when judging the industry relationships of a superstar surgeon generating important revenue and media attention for the hospital. Professional oversight will require strong leadership and buy-in from members. Although the public endorses self-regulation, I am pessimistic that our profession is committed to enforcing change. When giants in the field of orthopaedics start to have less influence than the device manufacturers, it demonstrates the enormity of the task (Sarmiento, 2003).

Ultimately, patients trust their surgeon to make decisions that prioritize the patient’s interests. Regardless of whether or not patients wanted disclosure or approved of financial relationships, patients in this study expect their surgeon to be virtuous. Patients expect their surgeon to manage their conflicts of interests appropriately and ethically. Patients do not want their relationship with their surgeons to dissolve into a “buyer-beware” model; rather, they expect their surgeon to make decisions regarding conflict of interest based on the surgeons knowledge, integrity and virtue. The community of orthopaedic surgeons need to strictly enforce relationships with manufacturers to avoid further embarrassments whilst maintaining important and productive industry collaborations, thereby maximizing utility.

This qualitative study has deepened my understanding of surgical patients’ opinions on financial relationships that can exist between surgeons and manufacturers. Surgeons should maximize utility by managing their financial relationships with manufacturers appropriately; allowing collaborations with manufacturers that do not threaten patient trust in the profession. Disclosure is necessary but is not a sufficient management strategy. Importantly, disclosure of financial
relationships to patients may shift the focus of the pre-operative discussion away from more important consequences and risks of the surgery. Patients continue to trust the surgical profession’s ability to self-regulate.

5.1 Limitations

This study has several limitations. This study was conducted in one urban academic hospital within a medical system that has a single provincially-run medical insurer and therefore the views provided may not be generalizable to patients in other settings. Patients that agreed to participation may have divergent views from those patients who declined to participate. In addition, only post-operative patients were interviewed. These patients may have different views from pre-operative patients. However, I chose to interview post-operative patients to minimize the risk of impacting surgical outcome by inducing worry and mistrust due to discussing this controversial topic. Another limitation was that patients required a great deal of education and coaching to comprehend the complex issues involved in the interview. However, this further demonstrates the weakness of disclosure to patients as a means to manage conflicts of interest (Weinfurt et al., 2006).
6 Quantitative Methods

6.1 Questionnaire Design

6.1.1 Concepts for exploration

Concepts to be explored in the questionnaire were developed in three steps. First, I derived concepts from the qualitative study. Approximately 30 concepts were created by examining individual codes that were patient derived during face-to-face interviews. Second, I developed concepts after I reviewed the pertinent literature and identified previously described concepts, themes and associations relating to patient views on financial relationships between healthcare providers and industry (please see chapter 2 for literature review). Finally, I examined previous patient or research participant surveys for suitable concepts and included them where appropriate (Hampson et al., 2006, Khan et al. 2007, Macneill et al., 2010, Tattersall et al., 2009, Edwards & Ballantyne, 2009). Ultimately, I developed 75 concepts for exploration.

6.1.2 Question and questionnaire formatting

6.1.2.1 Minimizing non-response

I developed the questions and questionnaire according to recent survey and questionnaire design research (see subsequent sections). Much of the literature is expert opinion; however whenever possible experimental research was incorporated into my survey design. Ultimately, formatting should limit non-response and response bias. In order to limit non-response, I formatted the questions and questionnaire to decrease the burden on the respondent. I reduced the number of concepts to be explored in the questionnaire. I removed any concept that would not make a significant contribution or was not fundamental to my thesis (Nieuwenhuijzen, 2005). I removed any concept where it was not clear how the data generated from that concept would be analyzed (Nieuwenhuijzen, 2005). The first draft of the questionnaire contained 75 items. The final questionnaire contained 48 items. To further reduce the burden on respondents, I avoided open-ended questions (Edwards, 2010). For the same reasons, I also avoided branching and matrix questions (Edwards, 2010). I removed items exploring sensitive patient demographics, such as race or religion, to increase question response. I placed other demographic questions at the end of the survey in a bid to increase question response and to reduce the influence sensitive
demographic questions had patient responses on opinion items (Boynton, Wood, & Greenhalgh, 2004).

I decided to use a Likert scale for the majority of my questions. Although not perfectly suitable for every concept, I had to balance the desire to satisfy both the reader of my research and the patient who would be answering the survey. I used a Likert scale of “strongly agree, agree, no opinion, disagree, strongly disagree”, which was used in a study on trust by Hall et al. (Hall et al., 2002). In that study, other scale formats proved to be too complex for respondents and produced distorted and unreliable responses (Hall et al. 2002). I used vertical response formats, as opposed to horizontal formats, as the former are less confusing for the respondent and this decreases the chance of having the wrong choice selected (Choi & Pak, 2005; Dillman, 2007). Through the use of experimental testing of a questionnaire completed by more than 1000 students, it was found that placing the location of instructions before rather than after response categories significantly increased response rates (Christian & Dillman, 2004). I therefore placed any stems or instructions according to this evidence. I directed respondents with phrases such as “START HERE” placed at the beginning of the questionnaire and symbols, such as arrows and lines to guide respondents from items to response categories (Dillman, 2007). In a further effort to decrease the burden on respondents, I used bold font for questions to differentiate them from response categories (Dillman, 2007).

Satisficing is a phenomenon that is defined as “giving an answer that is satisfactory but not optimal” (Streiner, 1995). Satisficing includes respondents choosing only the first option, only agreeing or only disagreeing to each item, merely endorsing the status quo, selecting the first reasonable answer, randomly selecting answers and choosing one response throughout the survey (Streiner, 1995). Krosnick described three factors that contribute to satisficing (Krosnick, 1999). Increased respondent burden, decreased respondent motivation and decreased respondent responsibility all contribute to satisficing (Krosnick, 1999). Satisficing is a problem that is not unique to self-administered surveys, rather in the self administered surveys satisficing will result in the choice of the first reasonable response whereas in an interview satisficing will result in the choice of the last reasonable response. In order to combat satisficing, I made alterations to the reading level of each question, made Likert scales regarding patient opinions consistent
throughout the questionnaire thereby lowering the task difficulty, and optimized the questionnaire and research protocol to increase respondent motivation to complete the questionnaire optimally.

To decrease the burden on the respondents and to combat satisficing, I analyzed my questions using the Flesch-Kincaid grade level and the modified Flesch reading ease score (Farr, Jenkins, & Paterson, 1951; Kincaid, Fishburne, Rogers, Chissom, 1975). The Flesch-Kincaid grade level is the lowest grade at which 50% of children in that grade obtain at least 35% on a Cloze test (Ley & Florio, 1996). A Cloze test is a test where every 5th word is left blank and the child has to guess the missing word (Ley & Florio, 1996). The modified Flesch reading ease score is the number of single syllable words out of 100 words (Farr et al., 1951). Experts in the field of survey design recommend targeting a Flesch-Kincaid grade level of six but this level was unrealistic for my survey (Streiner, 1995). The overall Flesch-Kincaid grade level for my survey was 11.5 with the modified Flesch reading ease 34.9 indicating that it is a difficult survey to read. However, the Likert scale of “strongly agree, agree, no opinion, disagree, strongly disagree” has a Flesch-Kincaid grade level and modified Flesch reading ease of 11.6 and 45 respectively. This gives an indication of the difficulty of balancing the reading level with the ease of completion using repeated Likert scales. I did however, use the Flesch-Kincaid grade level and modified Flesch reading ease score to lower the burden on the respondents wherever possible. This is evident by the introduction in the first draft of the questionnaire having a Flesch-Kincaid grade level of 6.7 and after multiple revisions the introduction in the final survey had a Flesch-Kincaid grade level of 5.6. I had to strive to have the questionnaire be understood by the respondents but still resonate with the academic community.

To increase motivation I used suggestions offered by Dillman (Dillman, 2007). I made the questionnaire appear short and easy to complete by producing it on 11" x 17" paper folded in half with a saddle stitch, which in Dillman's expert experience is the most effective booklet. The front page of the questionnaire was designed to showcase the sponsorship of the research by legitimate authorities: the New England Baptist Hospital, Mount Sinai Hospital, Sunnybrook Health Sciences Centre and the University of Toronto. Inconvenience was minimized by recruiting patients to complete the questionnaire while they waited to for their follow-up appointment. In
Canada, patients typically wait approximately 45 minutes to be seen by their surgeon. In the private clinics in the United States, this waiting time is reduced but still affords the majority of patients the time to complete a large proportion of the survey prior to their appointment. Patients were rewarded by being thanked both in writing at the completion of the questionnaire and through cash reimbursement. Singer et al. demonstrated that incentives of up to $20 do not appear to increase item non-response and do not affect sample composition in telephone surveys (Singer, Van Hoewyk, & Maher, 2000). On this basis, I think that the reimbursement of $10 to survey participants has not affected the composition of my study sample or the nature of the responses. The reimbursement was intended to offset the inconvenience of completing the questionnaire and the additional expense of prolonged parking.

6.1.3 Minimizing bias

After formatting the questions and questionnaire to minimize item non-response, I formatted the questionnaire and questions to reduce bias. In contrast to the survey conducted by Hampson et al. which was conducted as face-to-face interviews, I decided to use a self-administered questionnaire method (Hampson et al., 2006). Although self-administered questionnaires are susceptible to item non-response, they are less susceptible to social desirability bias than questionnaires conducted as face-to-face interviews (Edwards, 2010). Self-administered questionnaires offer anonymity to respondents, therefore allowing respondents to provide unpressed responses (Tourangeau & Smith, 1996; Aday, 2006). I collected no identifying information through the questionnaire to increase the respondents’ feeling of anonymity. I thought that anonymous self-administered questionnaires would minimize any social desirability bias. By removing the administrator in a face-to-face interview, I decreased the chance that the patient would feel pressure to answer questions that would satisfy the surgical team. Although satisficing can be evident in any questionnaire, this phenomenon is less pronounced in self-administered questionnaires than in face-to-face interviews (Bowling, 2005).

Visser et al. demonstrated that having a low response rate of 20% does not necessarily mean that a survey has a large non-response bias (Visser, Krosnick, Marquette, & Curtin, 1996). However, experts in survey design feel that non-response bias is a major source of error (Bowling, 2005). “The lower the response rates to a study, the greater the danger that the responders may differ
from non-respondents in their characteristics, which weakens the generalizability of the results”. Face-to-face interview surveys have the advantage, over self-administered questionnaires, of personal contact which can increase response rates (Edwards et al., 2002). However, personal contact is not exclusive to face-to-face interviews. I established personal contact by recruiting patients in arthroplasty follow-up clinics rather than distributing a mailed self-administered questionnaire. Monetary incentives can also increase the response rate, which was another aim of the $10 reimbursement provided to patients in my study (Edwards et al., 2002). To determine if my sample had a non-response bias, I collected information from patients that declined to participate including: gender, age, number of previous joint replacements, complications and reason for deciding not to participate. At the completion of data collection I would therefore be able to determine if there were major differences between the samples of respondents and non-respondents. This would help determine the generalizability of the study.

To further reduce bias, I avoided using leading or loaded phrases. Previous questionnaires have used the term “financial tie” which was felt to be a more neutral phrase then “conflicts of interest” (Hampson et al., 2006). Albeit an improvement, I felt that “financial tie” still had a negative connotation indicating that the surgeon was somehow bound to the device manufacturer devoid of independent thought or judgment. I therefore chose to use the term “financial relationship” to avoid this bias.

Question formatting can be a source of bias in questionnaires. In a Likert scale, an odd number of categories provide the respondent with a neutral option as opposed to an even number of categories that forces the respondent to commit (Bennett, 1975; Streiner, 1995). Not wanting to force patients to either agree or disagree with any particular item, I used a Likert scale containing five categories providing patients with a “no opinion” option. Tourangeau et al. demonstrated that respondents see the visual middle of the responses as the typical response and therefore suggested placing a line between the scale and non-response options (Tourangeau, Couper, & Conrad, 2004). I therefore placed a line between non-response options such as “I don't know”, “I can't remember” and “I don't want to answer this question” and the responses within the Likert scale.
Although the evidence for fully labeling scales (i.e. strongly agree, agree, no opinion, disagree, strongly disagree) is tentative, expert commentators prefer labeled scales and I therefore labeled my response options fully for each question (Krebs & Hoffmeyer-Zlotnik, 2010). Weng studied the reliability of Likert scales in a survey of more than 1000 students and found that questionnaires with fully labeled options were more reliable than questionnaires with only the endpoints of scales labeled (Weng, 2004). In addition, the study found that scales with more than three categories tended to be more reliable than scales with fewer response categories (Weng, 2004).

Numbering responses boxes is a common practice as it helps with data entry accuracy. However, the order of the numbering can produce systematic shifts in responses as respondents use any information provided to settle on their response choice (Schwartz et al., 1991). Therefore, I used unnumbered response boxes to avoid providing respondents with any extraneous information that may influence their responses (Krosnick, 1999). I also ensured that my response boxes were equidistant from each other as it has been demonstrated that unequal spaces between responses yields less reliable results (Christian & Dillman, 2004).

6.1.4 Pre-testing

The survey underwent five drafts prior to being subjected to two rounds of pre-testing. Drafts were reviewed and critiqued by: Dr Martin McKneally, an expert in bioethics and surgery; Dr Ross Upshur, an expert in bioethics and research methodology; Dr Earl Bogoch, an expert in orthopaedic surgery; and Drs. Nikki Woods and Dorcus Beaton, both experts in quantitative methodology.

I pre-tested the questionnaire to determine whether or not respondents could consistently understand and answer the questions in a way that I intended (Collins, 2003). Pre-testing involved two rounds. The first round involved completion of the questionnaire by knowledgeable colleagues. The questionnaire was completed by 20 graduate students in the Master’s of Health Sciences in Bioethics program administered by the Joint Centre of Bioethics at the University of Toronto. I sought feedback from the students with regards to ease of completion, question comprehension, grammatical or spelling errors. I made any necessary revisions prior to the
second round of pre-testing which involved cognitive interviews of patients who met the inclusion criteria for the study. Cognitive interviewing focuses on the completion of the questionnaire as opposed to the administration of the survey and recruitment of participants (Collins, 2003). I recruited patients for pre-testing at one of the participating surgeon’s follow-up arthroplasty clinic at a tertiary care hospital in Toronto. I obtained consent from patients for cognitive interviewing and I conducted the interviews. A potential drawback of cognitive interviewing is that respondents have to divide their attention between interviewer and the questionnaire (Dillman, 2007). For this reason, I chose a retrospective technique recommended by some commentators (Dillman, 2007). I was cognizant that a drawback of this technique was that respondents may show no visible signs of confusion while completing the questionnaire (Dillman, 2007). Examples of questions that I asked respondents following completing the questionnaire included: “How easy or difficult did you find this survey to complete?”, “Were there any parts of the survey that you found confusing?”, “Were you always able to find your preferred response to each statement or question?”, “Are there any changes to the survey that you feel would make it easier for patients like yourself to complete?”. I performed retrospective interviews to ensure that all information provided by and all items within the questionnaire were understood by the respondents, that all items were interpreted similarly by all respondents, that all items have an answer that can be marked by every respondent and that each respondent is likely to complete the questionnaire. Following cognitive testing of 8 patients, I felt that the questionnaire required no major revisions and that it could be finalized.

6.1.5 Survey reliability and validity

The reliability and validity of a questionnaire is particularly relevant when exploring latent variables, such as the intelligence quotient. Their relevance is less clear with questionnaires exploring attitudes and opinions. Reliability is the reproducibility and stability of the instrument within individuals or between individuals (Kimberlin & Winterstein, 2008). Reliability can be improved by having multiple items to measure the same concept (Kimberlin & Winterstein, 2008). However, the desire for reliability is in opposition to designing a questionnaire that is not only of minimal burden to the respondent but also explores all the domains of the topic. As my questionnaire was exploratory and descriptive and not meant to develop a reusable instrument, I
decided to focus on exploring the topic and all its domains rather than focus on a few domains with multiple items examining each concept. This incomplete knowledge of the reliability of my questionnaire is a limitation, albeit deliberate, of my study. Due to the time constraints of my thesis, it was not possible to retest the patients that had completed the questionnaire. However, not having to contact patients for retesting allowed us to omit identifying data which improved the patients’ feelings of anonymity. This promoted honest answers from respondents free from external pressure to satisfy.

Bennett described four types of validity (Bennett, 1975). Face validity determines whether an instrument appears to measure what it is designed to measure (Bennett, 1975). Expert opinion is used to judge whether a survey has face validity. My questionnaire has sufficient face validity determined by two experts in bioethics, Drs Upshur and McKneally. Content validity examines whether an instrument explores all the domains of the topic under study (Bennett, 1975). My questionnaire has strong content validity as it was constructed using concepts and themes brought about by my qualitative study, an extensive literature review and previous surveys that examined conflicts of interest. Construct validity explores whether the results of the survey are in accordance with previously published results (Bennett, 1975). Construct validity brings up the questions regarding the accuracy of the established model or theory. It also brings up questions regarding the generalizability of the theory. As I have pointed out in previous sections, previous research studies examining the views of surgical patients have significant methodological flaws (Khan et al., 2007). I am therefore reluctant to use previous published results as a method to establish validity. The final type of validity is criterion validity. Criterion validity is the concordance of the new instrument’s results with those of independent external criteria (Bennett, 1975). The only domain of my survey with established external criteria was trust (Dugan, Trachtenberg, & Hall, 2005). I therefore incorporated a five-item trust scale with minor modifications that are unlikely to disturb the items’ validity (Dugan et al., 2005). I had to change the order of the items in the scale as every contributing surgeon requested the item “Sometimes your surgeon cares more about what is convenient for (him/her) than about your medical needs” to come toward the end of the five-item scale rather than having it as one of the first items. As no external criteria exist for any other domains of my survey, a limitation of my survey is that I
am unable to establish criterion validity. However, I think that the face and content validity of my survey are sufficient to declare my survey valid.

6.1.6 Final instrument description

The final instrument contained 48 items in six domains: trust, awareness of and concern about financial relationships between surgeons and device manufacturers, opinions regarding oversight, attitudes towards disclosure of financial relationships, socio-demographic data and surgical characteristics. Items regarding concern about financial relationships were repeated at the end of the questionnaire to determine whether the questionnaire itself increased patients’ concern. (The complete questionnaire appears in the Appendix 4).

6.2 Power analysis

As this study was a cross-sectional observational survey intended to explore rather than explain patient views on the financial relationships between surgeons and manufacturers, I did not perform an a priori power calculation of power to calculate my sample size. Power calculations require an agreed upon outcome measure, an estimate of the variance of the outcome measure and an estimate of the clinically significant difference between comparative groups (Kent, 2001). As this was an exploratory survey, I did not have an agreed upon outcome measure, nor did I have a reliable estimate of its variance or clinically significant difference. Therefore, I based my sample size on precedent rather than an a priori power calculation (Hampson et al., 2006; Khan et al., 2007). I decided on a sample size of 250 patients from Canada and 250 patients from the United States. In previous research on the views of patients with cancer on financial relationships between researchers and industry, samples of this size were large enough to draw meaningful conclusions (Hampson et al., 2006).

6.3 Ethical considerations

I did not want my questionnaire to disturb the relationship between the patient and their surgeon. With a questionnaire exploring the topic at hand this was not always achievable and the risk was always present of disturbing the patient-surgeon relationship by decreasing the trust that a patient has in their surgeon. This risk was of particular concern to some surgeons that I approached to
allow patients to be recruited from their clinics. Four surgeons that I approached declined to be involved in this study because of this risk. In my judgment, this risk was small and the risk of patients losing trust in their surgeon from information provided by the survey was no more than information provided in the lay media. The 15 surgeons that chose to contribute patients agreed. However, I altered the research protocol to minimize this risk. I recruited only post-operative patients, who were at least three months from surgery, to complete the survey. I thought that pre-operative patients were at greater risk of having their trust in their surgeon damaged by the survey as this relationship is less established. I also believed that giving patients who were awaiting surgery a questionnaire regarding possible surgeon conflicts of interest may unnecessarily worry an already anxious patient. By recruiting only patients at least three months from surgery, I allowed patients to recover from the initial pain, decreased mobility and uncertainty of the post-operative period. I also decreased the chance of questionnaires being completed by patients distracted from pain in the post-operative course.

In order to reduce the risk of damage to the relationship between the patient and surgeon, I developed conflicts of interest statements to be given to patients following the completion of the survey. The statements described the financial relationships that the patient’s surgeon had with manufacturers. I left the distribution and wording of these statements to the discretion of each surgeon. Out of the 15 surgeons who contributed patients, only one surgeon chose to provide written conflicts of interest statements to patients that completed the questionnaire. Four other surgeons asked me to verbally communicate the surgeons’ relationships with manufacturers once a patient had completed the questionnaire. The five surgeons requesting conflicts of interest statements had no financial relationships with any orthopedic device manufacturer. The remaining 10 surgeons declined to provide patients with any information regarding their relationships with manufacturers. It should be noted that only half of the surgeons that declined to provide patients with conflicts of interest statements had financial relationships with manufacturers.

This study was reviewed and approved by research ethics boards at Sunnybrook Health Sciences Center, Mount Sinai Hospital and the New England Baptist Hospital. Consent was obtained through the completion of the survey. However, patients were provided with an information
letter describing the research prior to answering the survey. For data collected on patients that declined participation, two research ethics boards waived consent requirements as the data collected included no identifying information. In contrast, one research ethics board required formal written consent.

6.3.1 Inclusion criteria

Patients who were able to read English and who had undergone a hip or knee replacement performed by a participating surgeon at least 3 months prior.

6.4 Data Collection

Between November 2010 and March 2011, I recruited patients attending follow-up arthroplasty clinics at the Holland Orthopaedic and Arthritis Centre and Mount Sinai Hospital in Toronto and the New England Baptist Hospital in Boston. I approached every patient that met the inclusion criteria and invited them to participate in the study. I explained the purpose of the survey and assured anonymity and confidentiality. If the patient was interested, I provided them with a study information sheet, which offered a more detailed description of the study, and a questionnaire (Please see Appendix 5 for study information sheet). Consent was demonstrated by the patients’ completion of the questionnaire. Patients completed much of the questionnaire while they waited for their x-rays or for their appointment and completed the remainder after their appointment. I reimbursed patients $10 following completion of the questionnaire. I was therefore able to scan the questionnaire for missing responses before the patient left the clinic. If I found any items unanswered, I asked the patient to complete the unanswered item before I provided them with their reimbursement.

6.5 Data analysis

I have summarized my survey results and presented them according to the proportion of patients who had a response to each question. As I have data on patients that refused to participate I am able to demonstrate that there is no selection or sampling bias in my survey. I can therefore treat missing data (items that were not responded to) as data missing at random (Heitjan & Basu,
1996). I analyzed my data using SPSS (version 19.0). I performed univariate analysis to describe frequencies of responses to each item.

I thought that it was inappropriate to combine the samples from US and Canada as they were heterogeneous samples. I therefore examined the association between variables in the U.S. and Canadian samples separately. However, I did compare patient responses between the US and Canadian samples. Although some commentators treat Likert scales as interval data, I have taken a more traditional and conservative stance in my statistical analysis (Jamieson, 2004; Carifio & Perla, 2008). I treated my Likert scale as ordinal categorical data. I determined statistical significance using Chi square analysis. I used Somers’ D correlation coefficient to measure the association between patient responses and independent ordinal variables (e.g. level of education) (Somers, 1962). I used Cramer’s V measure of association to measure the association between patient responses and nominal variables (e.g. gender) (Kent, 2001). For these bivariate analyses I collapsed Likert scale into three response categories: agree, no opinion and disagree. I did this to simplify the discussion of my results and I do not feel that by collapsing my Likert scale that I have altered the conclusions of my research. In order to compare interval data to ordinal data I collapsed interval data into ordinal categories. For example, I collapsed age into ordinal categories of less than 50 years of age, 50-59 years of age, 60 to 69 years of age, 70 to 79 years of age, and greater than 80 years of age. I collapsed certain ordinal categories such as complications, education, and income, into binary categories in an effort to make my data set more manageable and more easily understood by the reader.
7 Quantitative Results

7.1 Patient characteristics

Demographic characteristics of U.S. and Canadian patients are provided in Table 4. Of the 285 U.S. patients who were approached, 251 agreed to complete the survey (an 88% response rate). Of the 273 Canadian patients who were approached, 252 agreed to complete the survey (a 92% response rate). In all, 499 of 502 surveys had complete data (a 99% completion rate).

7.1.1 U.S. patient characteristics

Of the 251 U.S. patients, 45% were men and 56% graduated from college or university (Table 4). 9% of patients were under 50 years of age, 27% of patients were between 50-59 years of age, 32% of patients were between 60-69 years of age, 24% of patients were between 70-79 years of age and approximately 8% of patients were 80 years old or over. This age and gender profile is consistent with previously published demographic data on hip and knee arthroplasty in the U.S. (Liu, González Della Valle, Besculides, Gaber, & Memtsoudis, 2009; Khatod et al., 2008). 58% of patients had had one joint replacement surgery, 29% of patients had had two joint replacement surgeries and 13% of patients had had 3 or more joint replacement surgeries. The majority of patients were more than 6 months from their most recent joint replacement surgery and had an income of greater than $50 000 per year. 19% of patients reported suffering a complication from one of their joint replacement surgeries.

7.1.2 Canadian patient characteristics

Of the 252 Canadian patients, 41% were men and 49% graduated from college or university (Table 4). 5% of patients were under 50 years of age, 25% of patients were between 50-59 years of age, 35% of patients were between 60-69 years of age, 25% of patients were between 70-79 years of age and approximately 10% of patients were 80 years old or over. This age and gender profile is consistent with registry data from the Canadian joint registry (CJRR, 2008). 59% of patients had had one joint replacement surgery, 28% of patients had had two joint replacement surgeries and 14% of patients had had 3 or more joint replacement surgeries. The majority of patients were more than 6 months from their most recent joint replacement surgery and had an
income of greater than $50 000 per year. 13% of patients reported suffering a complication from one of their joint replacement surgeries.

7.1.3 Differences between the U.S. and Canadian Samples

There were no statistical differences between the U.S. and Canadian samples in gender, age, annual income, number of joint replacement surgeries, and time since most recent surgery or post-operative complications. The U.S. patient sample contained a slightly higher proportion of patients with college or university degrees ($X^2=7.852, P=0.049$).

7.1.4 Non-respondent characteristics

Patients that refused participation had similar demographic and surgical characteristics to participants. The most common reason for not participating was “not interested” (54%). Other reasons given were “too busy” (15%), “don’t know anything about topic” (15%) and “too onerous” (12%). There were no differences between U.S. and Canadian non-respondents.

7.2 Patient awareness and concern about financial relationships

7.2.1 U.S. patient awareness and concern about financial relationships

54% of U.S. patients surveyed were aware that surgeons could have financial relationships with device manufacturers (Table 5). 70% of U.S. patients surveyed were aware that physicians could have financial relationships with pharmaceutical companies (Table 5). Only 6% of U.S. patients surveyed were worried about possible financial relationships between their surgeon and manufacturers (U.S. Table 6). At the end of the survey 17% of U.S. patients were worried about possible financial relationships between their surgeon and manufacturers (U.S. Table 6). Information provided on financial relationships between surgeons and manufacturers may have heightened awareness and resulted in the increased patient worry at the end of the survey.

7.2.2 Canadian patient awareness and concern about financial relationships

Only 35% of Canadian patients surveyed were aware that surgeons could have financial relationships with device manufacturers (Table 5). 55% of Canadian patients surveyed were aware that physicians could have financial relationships with pharmaceutical companies (Table
Table 4. Demographic and Clinical Characteristics of U.S. and Canadian Study Patients*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>U.S. Patients</th>
<th>Canadian Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(N=251) no. (%)</td>
<td>(N=252) no. (%)</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>113 (45)</td>
<td>104 (41)</td>
</tr>
<tr>
<td>Female</td>
<td>138 (55)</td>
<td>148 (59)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;50yr</td>
<td>22 (9)</td>
<td>13 (5)</td>
</tr>
<tr>
<td>50-59yr</td>
<td>67 (27)</td>
<td>64 (25)</td>
</tr>
<tr>
<td>60-69yr</td>
<td>81 (32)</td>
<td>87 (35)</td>
</tr>
<tr>
<td>70-79yr</td>
<td>59 (24)</td>
<td>64 (25)</td>
</tr>
<tr>
<td>≥80</td>
<td>21 (8)</td>
<td>23 (9)</td>
</tr>
<tr>
<td>Education†</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High School Graduate or Less</td>
<td>47 (19)</td>
<td>63 (26)</td>
</tr>
<tr>
<td>Some College/University</td>
<td>64 (26)</td>
<td>60 (25)</td>
</tr>
<tr>
<td>College/University Degree</td>
<td>62 (25)</td>
<td>67 (28)</td>
</tr>
<tr>
<td>Graduate or Professional Degree</td>
<td>76 (31)</td>
<td>50 (21)</td>
</tr>
<tr>
<td>Annual Income‡</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;$50,000</td>
<td>46 (22)</td>
<td>53 (27)</td>
</tr>
<tr>
<td>$50,000-74,999</td>
<td>47 (23)</td>
<td>45 (23)</td>
</tr>
<tr>
<td>$75,000-99,999</td>
<td>28 (13)</td>
<td>34 (17)</td>
</tr>
<tr>
<td>≥$100,000</td>
<td>86 (42)</td>
<td>64 (33)</td>
</tr>
<tr>
<td>Number of joint replacement surgeries</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 joint replacement surgery</td>
<td>146 (58)</td>
<td>148 (59)</td>
</tr>
<tr>
<td>2 joint replacement surgeries</td>
<td>73 (29)</td>
<td>69 (28)</td>
</tr>
<tr>
<td>3 or more joint replacement surgeries</td>
<td>32 (13)</td>
<td>34 (14)</td>
</tr>
<tr>
<td>Time since most recent joint replacement surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;6 months</td>
<td>67 (27)</td>
<td>66 (26)</td>
</tr>
<tr>
<td>6 months to 1 year</td>
<td>47 (19)</td>
<td>49 (19)</td>
</tr>
<tr>
<td>1 to 5 years</td>
<td>108 (43)</td>
<td>98 (40)</td>
</tr>
<tr>
<td>≥5 years</td>
<td>27 (11)</td>
<td>38 (15)</td>
</tr>
<tr>
<td>Complications resulting from any previous joint replacement surgery§</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>47 (19)</td>
<td>33 (14)</td>
</tr>
<tr>
<td>No</td>
<td>195 (81)</td>
<td>211 (87)</td>
</tr>
</tbody>
</table>

* Totals may vary due to missing data or patient refusal. Percentages may not total 100 because of rounding.
† The U.S. patient sample contained a slightly higher proportion of patients with college or university degrees (P=0.049).
‡ A total of 37 U.S. patients and 44 Canadian patients declined to state their annual income. 10 U.S. patients and 7 Canadian patients did not know their annual income.
§ Patient reported complications were limited to infections requiring revision surgery, fractures requiring revision surgery and revision surgery within 5 years of primary arthroplasty.
5). Only 6% of Canadian patients surveyed were worried about possible financial relationships between their surgeon and manufacturers (Table 6). At the end of the survey 22% of Canadian patients were worried about possible financial relationships between their surgeon and manufacturers (Table 6).

7.2.3 Differences between U.S. and Canadian patient awareness and concern about financial relationships

U.S. patients were more likely to be aware of financial relationships between surgeons and surgical device manufacturers than their Canadian counterparts ($X^2=17.842$, $P=0.0001$). U.S. patients were also more likely to be aware of financial relationships between doctors and drug companies ($X^2=13.359$, $P=0.001$). There were no differences between U.S. and Canadian patient concern about financial relationships, either at the beginning or at the end of the survey.

Table 5. U.S. and Canadian patient awareness of physicians’ and surgeons’ financial relationships with industry*

<table>
<thead>
<tr>
<th>Statement</th>
<th>Percent of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before today, you were aware that surgeons could have financial relationships with companies that make hip and knee replacements†</td>
<td>U.S. 54  Canada 36  U.S. 18  Canada 27  U.S. 28  Canada 38</td>
</tr>
<tr>
<td>Before today, you were aware that doctors could have financial relationships with drug companies‡</td>
<td>U.S. 70  Canada 55  U.S. 11  Canada 20  U.S. 19  Canada 25</td>
</tr>
</tbody>
</table>

* Percentages may not total 100 because of rounding.
†U.S. patients were more likely to be aware of financial relationships between surgeons and surgical device manufacturers than their Canadian counterparts ($P=0.0001$).
‡U.S. patients were more likely to be aware of financial relationships between doctors and drug companies ($P=0.001$).
7.3 Patient opinions regarding the appropriateness of financial relationships

7.3.1 U.S. patient opinions regarding the appropriateness of financial relationships

U.S. patients made the distinction between financial relationships that have the potential to be beneficial to patients versus those financial relationships that are profitable to surgeons and manufacturers alone. 69% of U.S. patients felt that it was appropriate for their surgeon to receive royalty payments for a patent on a product that their surgeon had designed (Table 7). 48% of U.S. patients felt that it was appropriate for their surgeon to receive payments from device manufacturers for consultant work that involved product improvement (Table 7). 46% of U.S. patients felt that it was appropriate for their surgeon to receive payments from device manufacturers for consultant work that involved education (Table 7). Only 11% of U.S. patients felt that gifts over $100 were appropriate for their surgeon to receive from a device manufacturer (Table 7). Only 20% of U.S. patients felt that gifts under $100 were appropriate for their surgeon to receive from a device manufacturer (Table 7). Examples of gifts from device manufacturers provided in the survey included: hotel costs covered at a conference; textbooks; and meals (See Appendix 4). Only 21% of U.S. patients felt that it was appropriate for their surgeon to own shares in a joint replacement manufacturing company whose products are used by their surgeon (Table 7).

7.3.2 Canadian patient opinions regarding the appropriateness of financial relationships

Like their U.S. counterparts, Canadian patients made the distinction between financial relationships that have the potential to be beneficial to patients versus those financial relationships that are profitable to surgeons and manufacturers alone. The majority of Canadian patients felt that it was appropriate for their surgeon to receive payments from device manufacturers for consultant work that involved education or product improvement (Table 7). Similarly, 66% of Canadian patients felt that it was appropriate for their surgeon to receive royalty payments for a patent (Table 7). Only 13% of Canadian patients felt that gifts over $100 were appropriate for their surgeon to receive from a device manufacturer (Table 7). Only 18% of
Canadian patients felt that gifts under $100 were appropriate for their surgeon to receive from a device manufacturer (Table 7). Similarly, only 22% of patients felt that it was appropriate for their surgeon to own shares in a joint replacement manufacturing company whose products are used by their surgeon (Table 7).

### Table 6. U.S. and Canadian patient concern about their surgeons’ financial relationships with manufacturers*

<table>
<thead>
<tr>
<th>Statement</th>
<th>Percent of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Before today, you were worried about financial relationships between <em>your</em> surgeon and the company that made your hip or knee replacement</td>
<td>U.S.</td>
</tr>
<tr>
<td></td>
<td>“Strongly Agree”</td>
</tr>
<tr>
<td></td>
<td>6</td>
</tr>
<tr>
<td>You are worried about financial relationships between <em>your</em> surgeon and the company that made your hip and knee replacement</td>
<td>17</td>
</tr>
</tbody>
</table>

* Percentages may not total 100 because of rounding.

### 7.3.3 Differences between U.S. and Canadian patient opinions regarding the appropriateness of financial relationships

There were no statistically significant differences in patient opinions regarding the appropriateness of financial relationships between the U.S. and Canadian samples.

### 7.4 Patient trust in their surgeon and views on their surgeon having financial relationships with manufacturers

#### 7.4.1 U.S. patient trust in their surgeon and views on their surgeon having financial relationships with manufacturers

At the beginning of the survey, 96% of U.S. patients stated that they had complete trust in their surgeon. Only 13% of U.S. patients felt that having financial relationships with device
manufacturers demonstrated that their surgeon was highly qualified (Table 8). Only 31% of U.S. patients would trust their surgeons’ recommendations less if their surgeon had financial relationships with manufacturers. Ultimately, 76% of U.S. patients felt that their surgeon would make the best choices for their health regardless of their surgeon having financial relationships with device manufacturers.

7.4.2 Canadian patient trust in their surgeon and views on their surgeon having financial relationships with manufacturers

At the beginning of the survey, 97% of Canadian patients stated that they had complete trust in their surgeon. Only 20% of Canadian patients felt that having financial relationships with device manufacturers demonstrated that their surgeon was highly qualified (Table 8). 36% of Canadian patients would trust their surgeons’ recommendations less if their surgeon had financial relationships with manufacturers. Ultimately, 74% of Canadian patients felt that their surgeon would make the best choices for their health regardless of their surgeon having financial relationships with device manufacturers.

7.4.3 Differences between U.S. and Canadian patient trust in their surgeon and views on their surgeon having financial relationships with manufacturers

The only difference between U.S. and Canadian patient trust in their surgeon and views on their surgeon having financial relationships with manufacturers was that Canadian patients were more likely to state that having financial relationships with the company that made their joint replacement shows that their surgeon is highly qualified ($X^2=8.979$, $P=0.012$). It should be noted that only 20% of Canadian patients agreed with this statement.

7.5 Patient opinions regarding oversight of financial relationships

7.5.1 U.S. patient opinions regarding oversight of financial relationships

Of the U.S. patients surveyed, a vast majority of patients wanted their surgeon, a conflict of interest committee at their surgeon’s hospital or their surgeon’s professional regulatory body to ensure that financial relationships are appropriate (U.S. Table 9). Only 26% of U.S. patients wanted a government watchdog created to monitor financial relationships (U.S. Table 9).
Table 7. U.S. and Canadian patient views on the type of financial relationships between surgeons and manufacturers*

<table>
<thead>
<tr>
<th>Statement</th>
<th>Percent of patients</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>“Strongly Agree”</td>
<td>“Agree”</td>
<td>No Opinion</td>
<td>“Disagree”</td>
<td>“Strongly Disagree”</td>
</tr>
<tr>
<td></td>
<td>US</td>
<td>Canada</td>
<td>US</td>
<td>Canada</td>
<td>US</td>
</tr>
<tr>
<td>Own shares in the company that made your hip or knee replacement</td>
<td>21</td>
<td>22</td>
<td>30</td>
<td>30</td>
<td>49</td>
</tr>
<tr>
<td>Get payments from the company for offering advice to the company in your surgeon’s area of expertise</td>
<td>48</td>
<td>53</td>
<td>21</td>
<td>22</td>
<td>32</td>
</tr>
<tr>
<td>Get payments from the company to give lectures, including some that might discuss the company’s products</td>
<td>46</td>
<td>53</td>
<td>23</td>
<td>21</td>
<td>31</td>
</tr>
<tr>
<td>Get payments from the company for a patent on a product that your surgeon designed</td>
<td>69</td>
<td>66</td>
<td>15</td>
<td>19</td>
<td>16</td>
</tr>
<tr>
<td>Get gifts worth more than $100 from the company that made your hip or knee replacement</td>
<td>11</td>
<td>13</td>
<td>26</td>
<td>28</td>
<td>63</td>
</tr>
<tr>
<td>Get gifts worth less than $100 from the company that made your hip or knee replacement</td>
<td>20</td>
<td>18</td>
<td>29</td>
<td>35</td>
<td>51</td>
</tr>
</tbody>
</table>

* Percentages may not total 100 because of rounding.

7.5.2 Canadian patient opinions regarding oversight of financial relationships

In agreement with their U.S. counterparts, a vast majority of patients wanted their surgeon, a conflict of interest committee at their surgeon’s hospital or their surgeon’s professional organization to ensure that financial relationships are appropriate (Table 9). Interestingly, only 35% of Canadian patients wanted a government watchdog created to monitor financial relationships (Table 9).
Table 8. U.S. and Canadian patient trust in their surgeon and views on their surgeon having financial relationships with manufacturers*

<table>
<thead>
<tr>
<th>Statement</th>
<th>Percent of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>“Strongly Agree” and “Agree”</td>
</tr>
<tr>
<td></td>
<td>U.S.</td>
</tr>
<tr>
<td>All in all, you have complete trust in your surgeon†</td>
<td>96</td>
</tr>
<tr>
<td>Having financial relationships with the company that made your joint</td>
<td>13</td>
</tr>
<tr>
<td>replacement shows that your surgeon is highly qualified‡</td>
<td></td>
</tr>
<tr>
<td>Having financial relationships with the company that made your joint</td>
<td>31</td>
</tr>
<tr>
<td>replacement makes you trust your surgeon’s recommendations less</td>
<td></td>
</tr>
<tr>
<td>Your surgeon will make the best choices for your health whether or not</td>
<td>76</td>
</tr>
<tr>
<td>he/she has financial relationships with the company that made your joint</td>
<td></td>
</tr>
<tr>
<td>replacement</td>
<td></td>
</tr>
</tbody>
</table>

* Percentages may not total 100 because of rounding.
† This item was placed before any information or statements on financial relationships between surgeons and manufacturers to establish baseline trust.
‡ Canadian patients were more likely to state that having financial relationships with the company that made their joint replacement shows that their surgeon is highly qualified (P=0.012).

7.5.3 Differences between U.S. and Canadian patient opinions regarding oversight of financial relationships

There were no statistically significant differences in patient opinions regarding oversight of financial relationships between the U.S. and Canadian samples.

7.6 Patient attitudes towards disclosure of their surgeon’s financial relationships with manufacturers to patients

7.6.1 U.S. patient towards disclosure of their surgeon’s financial relationships with manufacturers to patients

Only 28% of U.S. patients feel that knowing their surgeon’s financial relationships with manufacturers would help with their pre-operative decision-making (Table 10). 38% of U.S.
patients thought that their surgeon should place his or her financial relationships on a publically accessible website and only 33% of U.S. patients would visit such a website prior to deciding to go ahead with surgery. 50% of U.S. patients would not want to think about financial relationships before surgery as there are more important risks to think about. 50% of U.S. patients would trust have more trust in their surgeon if their surgeon’s financial relationships were disclosed his or her financial relationships (either verbally, by pamphlet or website) than if these relationships remained undisclosed.

**Table 9. U.S. and Canadian patient views on oversight of their surgeon’s financial relationships with manufacturers***

<table>
<thead>
<tr>
<th>Statement</th>
<th>Percent of patients</th>
<th>U.S.</th>
<th>Canada</th>
<th>U.S.</th>
<th>Canada</th>
<th>U.S.</th>
<th>Canada</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your surgeon should make sure these relationships are appropriate</td>
<td>“Strongly Agree” and “Agree”</td>
<td>81</td>
<td>78</td>
<td>8</td>
<td>6</td>
<td>11</td>
<td>16</td>
</tr>
<tr>
<td>A new committee should be created at your surgeon’s hospital to make sure these relationships are appropriate</td>
<td>“Strongly Agree” and “Agree”</td>
<td>60</td>
<td>61</td>
<td>26</td>
<td>23</td>
<td>14</td>
<td>15</td>
</tr>
<tr>
<td>Your surgeon’s professional organization should make sure these relationships are appropriate</td>
<td>“Strongly Agree” and “Agree”</td>
<td>83</td>
<td>83</td>
<td>9</td>
<td>12</td>
<td>8</td>
<td>4</td>
</tr>
<tr>
<td>A new government watchdog should be created to make sure these relationships are appropriate</td>
<td>“Strongly Agree” and “Agree”</td>
<td>26</td>
<td>35</td>
<td>28</td>
<td>26</td>
<td>47</td>
<td>39</td>
</tr>
</tbody>
</table>

* Percentages may not total 100 because of rounding.

7.6.2 Canadian patient attitudes towards disclosure of their surgeon’s financial relationships with manufacturers to patients

Only 25% of Canadian patients feel that knowing their surgeon’s financial relationships with manufacturers would help with their pre-operative decision-making (Table 10). 30% of Canadian patients thought that their surgeon should place his or her financial relationships on a publically
accessible website and only 32% of Canadian patients would visit such a website prior to deciding to go ahead with surgery. 55% of Canadian patients would not want to think about financial relationships before surgery as there are more important risks to think about. 40% of Canadian patients would trust have more trust in their surgeon if their surgeon’s financial relationships were disclosed his or her financial relationships (either verbally, by pamphlet or website) than if these relationships remained undisclosed.

7.6.3 Differences between U.S. and Canadian patient towards disclosure of their surgeon’s financial relationships with manufacturers to patients

U.S. patients were more likely to state that their surgeon should put any financial relationships with manufacturers on a public website than their Canadian counterparts ($X^2=6.126, P=0.047$). U.S. patients were more likely to state that they would have more trust in their surgeon following disclosure of financial relationships with manufacturers than their Canadian counterparts ($X^2=8.445, P=0.015$).

7.7 Predictors of patient attitudes and preferences

7.7.1 Predictors of U.S. patient attitudes and preferences

U.S. patients who had graduated from college or university were likely to disagree with their surgeon receiving gifts worth more than $100 from the company that supplied their joint replacement (72% of those who graduated from college or university thought that receiving gifts worth more than $100 was inappropriate compared to 54% of those who had not graduated from college or university, Somers’ $d=-0.146, P=0.020$).

U.S. patients who were aware that either surgeon or physician financial relationships with manufacturers could exist prior to participation (hereafter referred to as aware patients) were more likely to agree that financial relationships that had the potential to benefit patients were appropriate (54% of aware patients thought that being a consultant was appropriate compared to just 31% of unaware patients, Somers’ $d=0.176, P=0.014$; 52% of aware patients thought that giving lectures on behalf of a company was appropriate compared to only 31% of unaware patients, Somers’ $d=0.180, P=0.013$; 75% of aware patients felt that being paid royalties for a patent was appropriate compared to 54% of unaware patients, Somers’ $d=0.185, P=0.007$).
Table 10. U.S. and Canadian patient attitudes towards disclosure of their surgeon’s financial relationships with manufacturers to patients*

<table>
<thead>
<tr>
<th>Statement</th>
<th>Percent of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>“Strongly Agree” and “Agree”</td>
</tr>
<tr>
<td></td>
<td>U.S.</td>
</tr>
<tr>
<td>Knowing your surgeon’s financial relationships would have helped you to make better decisions about your surgery</td>
<td>28.0</td>
</tr>
<tr>
<td>Before surgery, your surgeon should verbally tell you about his/her financial relationships with companies involved in your surgery</td>
<td>47.0</td>
</tr>
<tr>
<td>Before surgery, you surgeon should give you a printed pamphlet telling you about his/her financial relationships with companies</td>
<td>42.0</td>
</tr>
<tr>
<td>Your surgeon should put his/her financial relationships with companies on a public website†</td>
<td>38.0</td>
</tr>
<tr>
<td>If you surgeon’s financial relationships were on a public website, you would look at the website before deciding to go ahead with the operation</td>
<td>33.0</td>
</tr>
<tr>
<td>You would not want to think about these financial relationships before surgery because there are more important risks to think about‡</td>
<td>50.0</td>
</tr>
<tr>
<td>If your surgeon told you about his/her financial relationships (either verbally, by pamphlet or website) you would have more trust in your surgeon than if he or she didn’t tell you</td>
<td>50.0</td>
</tr>
</tbody>
</table>

* Percentages may not total 100 because of rounding.
†U.S. patients were more likely to state that their surgeon should put any financial relationships with manufacturers on a public website than their Canadian counterparts ($X^2$=6.126, P=0.047).
‡U.S. patients were more likely to state that they would have more trust in their surgeon following disclosure of financial relationships with manufacturers than their Canadian counterparts ($X^2$=8.445, P=0.015).
Aware and unaware U.S. patients were equally likely to agree that gifts were inappropriate. However, patients who were aware of either surgeon or physician financial relationships with manufacturers were more likely to find share ownership in a device manufacturer appropriate (28% of those aware of financial relationships felt that share ownership was appropriate compared to 14% of unaware patients, Somers’ d=0.154, P=0.024).

At the end of the survey, patients with complications were more likely to be worried about their surgeon’s possible financial relationships with manufacturers (22% of patients with complications were worried about their surgeon’s possible financial relationships with manufacturers compared to 15% of patients without complications, Somers’ d=0.195, P=0.008). Patients with complications were no more likely to be worried than patients without complications at the beginning of the survey.

There was no consistent association among such factors as age, gender, income, number of surgeries, or time since surgery on U.S. patients’ views on financial relationships between surgeons and device manufacturers.

### 7.7.2 Predictors of Canadian patient attitudes and preferences

Level of education was associated with awareness of either surgeon or physician financial relationships. Canadian patients who had graduated from college or university were significantly more likely to be aware that financial relationships could exist between health care providers (surgeons or physicians) with manufacturers (69% of those with a college or university degree, 48% of those without a college or university degree, Somers’ d=0.213, P=0.001). Patients who were aware of either surgeon or physician financial relationships with manufacturers were no more likely to be worried by potential financial relationships between their surgeon and manufacturers than unaware patients.

Canadian patients who had graduated from college or university were likely to disagree with their surgeon receiving gifts worth more than $100 from the company that supplied their joint replacement (67% of those who graduated from college or university thought that receiving gifts worth more than $100 was inappropriate compared to 54% of those who had not graduated from college or university, Somers’ d=-0.145, P=0.023).
Similar to their U.S. counterparts, aware patients in the Canadian sample were more likely than unaware patients to agree that financial relationships that had the potential to benefit patients were appropriate (64% of aware patients thought that being a consultant was appropriate compared to just 37% of unaware patients, Somers’ d=0.237, P<0.001; 58% of aware patients thought that giving lectures on behalf of a company was appropriate compared to only 45% of unaware patients, Somers’ d=0.140, P=0.037; 77% of aware patients felt that being paid royalties for a patent was appropriate compared to 51% of unaware patients, Somers’ d=0.245, P<0.001). Aware and unaware Canadian patients were equally likely to agree that gifts were inappropriate.

There was no consistent association among such factors as age, gender, income, number of surgeries, time since surgery or complications on Canadian patients’ awareness of or views on financial relationships between surgeons and device manufacturers.
8 Quantitative discussion

Despite media coverage of the kickback scandal (Abelson, 2006; Abelson, 2009; Feder, 2007; Feder, 2008; Harris, 2009; Kelly 2009), only 54% of U.S. patients and 36% of Canadian patients were aware that financial relationships between surgeons and manufacturers could exist. These differences in U.S. and Canadian patient awareness of financial relationships between surgeons and manufacturers are most likely due to differences in media coverage in the US and Canada. In contrast to Canadian newspapers, the U.S. lay press has extensively covered allegations of kickbacks from manufacturers to surgeons (Abelson, 2006; Abelson, 2009; Feder, 2007; Feder, 2008; Harris, 2009; Kelly 2009). As expected from the qualitative study, there was greater awareness of financial relationships with industry among physicians than among surgeons in both the U.S. and Canadian samples. Greater publicity of physicians’ relationships with the pharmaceutical industry compared to surgeon-manufacturer relationships may contribute to this difference. Another difference may also contribute to this finding. Interactions between pharmaceutical representatives may be witnessed by patients in physicians’ offices. In contrast, interactions between surgeons and device manufacturer representatives often occur in the operating room where patients may be unaware of the roles of each person in a busy operating room.

Canadian patients with tertiary education were more likely to be aware of financial relationships between surgeons and manufacturers. There are a number of factors that may contribute to this association. First, patients with tertiary education may make the connection that relationships between surgeons and device manufacturers would be no different than relationships between physicians and pharmaceutical manufacturers. Second, patients with tertiary education may read more broadly and therefore be more aware of happenings in the U.S. and kickback scandals. Because of the differences in media coverage of surgeon-manufacturer relationships in Canada and the US, patients would have learned about these relationships by reading U.S. newspapers or watching U.S. news. The reason we do not see an association between education and awareness among U.S. patients may be that even U.S. patients without tertiary education read or watch national news and U.S. national news covered the kickback scandal.
Both U.S. and Canadian patients made distinctions between the appropriateness of financial relationships that had the potential to benefit patients, versus financial relationships that only had the potential to benefit surgeons and/or manufacturers. Most patients in both samples thought that royalty payments from a manufacturer, based on patents held by a surgeon, were appropriate. Roughly half the patients in both samples thought there was appropriate for surgeons to work as consultants helping manufacturers with product development and design or education. These results are consistent with a previous survey of surgical patients (Khan et al., 2007), and a survey of cancer patients enrolled in cancer research trials (Hampson et al., 2006). Patients may feel that relationships that improve product design ultimately lead to improved patient outcomes (Weinfurt et al., 2006). This view would be consistent with the patients in the qualitative study who acknowledged that surgeon input is vital in the discovery of new and improvement of current surgical treatments. Moreover, this view would be consistent with opinions of thoughtful commentators and legislators, such as Dr. Jorge Galante and Sen. Herb Kohl, who suggest that collaborations between surgeons and manufacturers can be productive and legitimate (i.e. royalty payments for patents) and should not be painted with the same brush as those relationships that are not productive (i.e. gifts) (Surgeons for sale, 2008, p. 1; Jacobs et al, 2006, p. 1653).

Patients who were aware of the existence of financial relationships between health care providers and industry prior to participating in this study were more likely than unaware patients to hold the view that relationships that improve product design ultimately lead to improved patient outcomes. However, aware and unaware U.S. and Canadian patients were equally likely to agree that gifts were inappropriate. This suggests that educating patients about the potential benefits and perils of financial relationships between surgeons and manufacturers could possibly help to maintain public trust in our profession and allow continued beneficial collaboration with industry. Future prospective studies may aid in determining whether education of patients regarding financial relationships with industry can achieve these goals.

Financial relationships that can occur between surgeons and manufacturers are not a source of worry to surgical patients. Although there were more patients worried about possible financial relationships between the surgeon and manufacturers at the end of the survey in both samples,
the proportion of worried patients remained below 25%. Even patients who were aware of possible financial relationships between surgeons and manufacturers were not concerned. This is likely due to the trust patients have in their surgeon. At the beginning of the survey the patients completed a trust scale that I modified which was originally developed at Wake Forest University School of Medicine and used in a previous survey (Dugan et al., 2005; Hampson et al., 2006). Based on this trust scale, more than 95% patients trusted their surgeon implicitly. When asked specifically regarding the health care choices, roughly 75% of patients in both the US and Canada trusted that their surgeon would act in the patient’s best interest regardless of financial relationships with manufacturers. Only a third of patients in both samples thought that the trust in their surgeon would be diminished by financial relationships between their surgeon and a manufacturer. Patients may find it psychologically advantageous to trust that their surgeon would not let financial relationships with manufacturers trump the patient's interests (Hampson et al., 2006). Although the patients in this survey were treated for non-life threatening illness, their concern about financial relationships and their trust in their health care providers are similar to the attitudes of cancer patients (Hampson et al., 2006). It is important to note that only 1% of patients surveyed in this study were ever told about their surgeon’s financial relationships prior to the survey. Therefore, the trust that surveyed patients had in their surgeon was not influenced by pre-existing knowledge of their surgeon’s financial relationships with a manufacturer.

In my survey, trust in their surgeon seems to limit the usefulness of disclosure to patients or to the public as a sole method of ensuring appropriate surgeon-manufacturer financial relationships. An insufficient management strategy at best, disclosure assumes an unlikely capacity to critically evaluate a fiduciary’s decision-making. Trusting patients may be unable to critically evaluate their surgeon’s financial relationships with manufacturers to determine whether or not these will influence their care. The views of surgical patients in my study highlight the practical shortcomings of U.S. disclosure legislation as a sole method of ensuring appropriate surgeon-manufacturer financial relationships. Only 25% of patients thought that pre-operative disclosure of conflicts of interest would improve their pre-operative decision making. As seen in my qualitative study, patients may view disclosure as an unnecessary burden, shifting focus away from more important aspects of care. Previous research is consistent with these findings as patients place their healthcare provider’s conflicts of interest low on their decision-making
priority list (Weinfurt et al., 2008). In contrast to the results from this survey, a review of previously conducted quantitative studies reported a strong patient desire for disclosure (Licurse et al., 2010). However, this review included studies that did not examine vulnerable patients facing surgery with major surgical risks and consequences as a significant component of their decision making process. Most of the studies in the review examined the opinions of potential patients, potential research participants or members of the general public, who have few if any competing worries. Patients in this survey had an outlook consistent with vulnerable patient groups (Hampson et al, 2006; Grady et al., 2006). Vulnerable research participants often rejected the idea of disclosure as they felt it did not help them in the decision to participate and they felt it added an extra burden that they would rather not deal with (Grady et al., 2006).

U.S. disclosure legislation may be limited practically by patient desire and ability to access their surgeon’s financial relationships with manufacturers pre-operatively. Only a third of patients would visit a website disclosing their surgeon’s financial relationships with manufacturers prior to surgery. This is consistent with the number of elderly patients with arthritis have access to the Internet (Tak & Hong, 2005). This data limits the impact such a website will have on deterring inappropriate financial relationships if no other methods of oversight are established. In the US, the Physician Payment Sunshine Provision will ensure that all significant financial relationships between U.S. healthcare providers and industry will be available on publically-searchable websites by September 30th 2013 (PPAC, 2010). To my knowledge, no other country has passed similar legislation. Although a publicly accessible website has the potential to inform patients about a surgeon’s financial relationships with manufacturers, it is unclear how these websites will benefit patients who have limited access to the internet (Tak & Hong, 2005).

From a surgeon-patient relationship standpoint, however, U.S. surgeons may promote trust by disclosure of financial relationships with manufacturers to their patients. There are no clear answers as to which the most appropriate method of disclosure to patients is. Although not clear from the results from this survey, a pamphlet may indeed be the best solution as it allows patients who do feel that it would aid in their pre-operative decision making to ask questions but does not disrupt patients that do not want disclosure of financial relationships to shift their focus from more important aspects of the pre-operative discussion.
A concern I had about disclosure of financial relationships with manufacturers to patients was that patients would view these relationships favourably, like endorsement deals for professional athletes. This concern is not supported by the survey data. Only 13% of US patients in 20% of Canadian patients thought that having financial relationships with manufacturers demonstrated that their surgeon was highly qualified. The study was not designed to determine whether this sentiment is consistent across patients of all the surgeons who contributed to the study. A new study may be able to shed light on whether patients of renowned and experienced surgeons have similar opinions in this regard to patients of inexperience surgeons.

U.S. and Canadian patients strongly endorse oversight of financial relationships between surgeons and manufacturers by the surgeon’s professional organizations. This attitude, along with the majority of patients wanting their surgeons to ensure that their financial relationships with manufacturers are appropriate, indicates that patients continue to trust our ability to self regulate. Despite the kickback scandal and multiple media reports regarding inappropriate financial relationships between surgeons and manufacturers, the surgical community still maintains the public’s trust. The establishment of professional oversight committees would provide critical review of disclosed financial relationships. Patient confidence in the profession could be maintained, future kickback scandals could be avoided, and beneficial collaborations between physicians and industry could continue.

A majority of patients felt that oversight of financial relationships should occur at the hospital level. I have concerns with this level of oversight. Although most likely the most convenient of level of oversight, I do not believe that a hospital committee could effectively monitor the financial relationships between one of the hospital’s surgeon superstars and a manufacturer. The hospital would be faced with their own conflicts of interest and with the economic climate of the present day, the hospital may have difficulty prohibiting a financial relationship that could jeopardize the hospitals finances. Interestingly, U.S. and Canadian patients were sceptical of government involvement in oversight of these financial relationships.

Although the majority of patients do not seem worried about financial relationships between surgeons and manufacturers, a substantial minority are worried. Moreover, a substantial minority
do want disclosure of their surgeon’s financial relationships with manufacturers. It may seem that the views of the patients in the minority have not been sufficiently accommodated in my suggestion of professional oversight to manage financial relationships between surgeons and manufacturers. However, many vulnerable patients in a previous survey felt that merely knowing that an oversight system was in place was sufficient in allaying their fears regarding their health care providers’ relationships with industry (Hampson et al., 2006). I propose, therefore, that professional oversight of these relationships would diminish this minority’s concerns regarding financial relationships between surgeons and manufacturers and quell their desire for disclosure.

In this quantitative study, surgical patients approved of financial relationships that had the potential to benefit patients but disapproved of those relationships that would benefit only the surgeon and the manufacturer. Patients did not endorse disclosure as a sole method of managing these relationships but favoured oversight by the profession.

8.1 Limitations

My study had several limitations. First, I included only post-operative patients. These patients had established relationships with their surgeons. Therefore, these results may not be consistent with the opinions of pre-operative patients choosing their surgeon. I made the decision to limit the study to post-operative patients in order to uphold the ethical principle of nonmaleficence. In other words, I excluded pre-operative patients as I did not want to damage patient trust in their surgeon and possibly affect patients’ post-operative outcomes. In addition, I reasoned that post-operative patients have the experience and knowledge of what information would have been helpful to them pre-operatively. Many surgeons had misgivings about approaching pre-operative patients and it is quite possible that I would not have had any contributing surgeons if I had decided to include pre-operative patients.

Second, my findings may not apply to surgical patients generally. The opinions of patients who have undergone total joint replacement surgery might differ from those of patients who undergo surgery for other reasons. Total joint replacement does however represent a class of common and widely practiced procedures that depend on collaborative interaction with manufacturers.
Third, in order to maximize my survey response and completion rates, I had to limit the length of my survey by omitting concepts to explore. In particular, I was not able to separate gifts that I thought were more worthy from gifts that I thought were less worthy. I believe that there is a difference between a peer-reviewed textbook provided from a manufacturer than a luxury vacation for two disguised as a continuing medical educational event. Unfortunately, due to space constraints on the survey, I had to separate gifts merely on whether they were more or less than a $100. Although I provided examples of gifts in the survey (i.e. “gets hotel costs covered by a company at a conference”, “gets free textbooks from a company”, “gets free meals from a company”), I am not able to determine from this survey if patients view different types of gifts differently.

Finally, although my survey has an extremely high response rate, it should be noted that 36% of non-respondents came from one surgeon’s clinic. This is the only clinic where I did not recruit patients. Rather, the surgeon secretaries recruited patients with a response rate of 33%. I do not believe that this is due to any inherent differences between this surgeon’s patients and the rest of the study population. Rather, I believe that this is due to a difference in the enthusiasm of the recruiter. In addition to my enthusiasm, I have a vested interest in the success of the study. This is in contrast to the surgeon’s secretaries, for whom recruiting patients was just another chore to complete during a busy day.
9 Conclusion and future directions

9.1 Conclusion

In both the qualitative and quantitative studies, the majority of patients support financial relationships between surgeons and manufacturers that have the potential to benefit current or future patients (e.g. patents, research consultancy, and educational consultancy). The majority of patients do not support relationships that have no clear potential to benefit current or future patients (e.g. stock options and gifts to surgeons). These views are consistent with previous research, and the opinions of thoughtful commentators and legislators (Khan et al., 2007, Jastifer & Roberts, 2009; Crigger et al., 2010; Macneill et al, 2010, Surgeons for sale, 2008; Jacobs et al, 2006). These findings suggest that prohibition of all types of financial relationships between surgeons and manufacturers may not be necessary to maintain the public’s trust in our profession. Other methods of managing relationships with manufacturers are needed to allow beneficial surgeon-manufacturer collaboration without the destruction of public trust in the profession.

The vast majority of patients trust their surgeons and believe that they will make patient-centered decisions regardless of having financial relationships with manufacturers. Because of this trust and belief, disclosure of financial relationships to patients is unlikely to be any more effective in managing financial relationships between surgeons and manufacturers than the status quo (i.e. self-regulation by individual surgeons). Furthermore, most patients do not feel that disclosure would aid in their pre-operative decision making and may actually shift focus away from more important aspects of the pre-operative discussion. The majority of patients undergoing total joint replacement would not visit a website that disclosed financial relationships between their surgeon and manufacturers, further weakening disclosure as a management strategy. Based on my qualitative and quantitative studies, disclosure alone, without oversight, is an ineffective management strategy.

In both my qualitative and quantitative studies, the vast majority of patients supported the idea of oversight. Interestingly, professional oversight, and not government oversight, was supported by the majority of patients. Despite recent scandals that have placed financial relationships with
manufacturers under the media spotlight, patients continue to have trust in their surgeons and the surgical profession’s ability to self-regulate.

In order to maximize utility, surgeons are morally responsible to maintain trust and build their trustworthiness (Rhodes & Strain, 2000). The surgical profession, therefore, has to have the maintenance and promotion of trust as a primary focus (Pellegrino & Thomasma, 1993). Licensure, credentials, continued medical education and re-licensure are all tools to promote trustworthiness and maintain public trust (Pellegrino & Thomasma, 1993). However, the surgical profession has a responsibility to monitor members’ activities and prohibit any behavior that damages the trustworthiness of the profession. In order to maximize utility, I believe that the surgical profession is obligated to monitor financial relationships between surgeons and manufacturers as they have the potential to undermine the trustworthiness of the profession. A system of oversight of financial relationships between surgeons and manufacturers is necessary. Such oversight would maximize utility by ensuring that past mistakes that resulted in allegations of kickbacks are avoided, that beneficial collaborations between surgeons and manufacturers are fostered, and that public trust is maintained. Consistent with the views of the majority of patients in both my studies, I believe that this oversight can be reliably performed through professional self-regulation. Professional organizations (e.g. AAOS), through expert members, have the necessary expertise to evaluate financial relationships appropriately. However, because membership is voluntary these professional organizations may lack the necessary authority to enforce significant sanctions on non-compliant members. Provincial/state medical regulatory boards (e.g. CPSO) may be in better positions to provide oversight of financial relationships between its members and manufacturers. These boards have the necessary authority and the necessary expertise, through its members, to evaluate financial relationships appropriately. Obviously, disclosure to the professional organizations of financial relationships between surgeons and manufacturers is a necessary first step in this oversight process. The US will have this mandated disclosure by 2013 (PPAC, 2010). Canada should consider legislation that enforces mandatory disclosure of financial relationships between surgeons and manufacturers to professional organizations (e.g. AAOS) and provincial/state medical regulatory boards (e.g. CPSO) to allow oversight of these relationships using utilitarian calculus to maximize utility.
Galante’s classification of financial relationships that can exist between surgeons and manufacturers may allow oversight committees to use utilitarian calculus with empirical evidence (e.g. data from my studies) to determine whether a financial relationship should be prohibited, permitted, or permitted with mitigating conditions (e.g. disclosure to patients, reimbursement limits) (Jacobs et al., 2006). For example, following this utilitarian approach, type 1 financial relationships (e.g. royalties for patents) may be permitted as the utility from future patients benefiting from scientific advancements added to the financial remuneration for the surgeon outweighs the disutility caused by the appearance of conflict of interest on patient trust and the potential for the surgeon-designer to use a device for reasons of financial gain rather than clinical indication. The potential for surgeon-designer bias may be further mitigated by a restriction that ensures that no financial payments be received by the surgeon-designer for any device implanted in his or her institution (Jacobs et al., 2006).

Type 2 financial relationships (e.g. consulting agreements) may be permitted as the utility generated by both financial remuneration for the surgeon and the improvement in product design outweighs the risk of surgeon bias and the possible damage to patient trust in the surgical profession over perceived conflicts of interest. The potential for surgeon bias may be mitigated by surgeon reimbursement restricted to an hourly rate no higher than what the surgeon would receive while operating. This has already been implemented by the US Anti-Kickback statute, where surgeons are entitled to a maximum of $500/hr for work performed on behalf of manufacturers (Surgeons for sale, 2008).

Type 3 financial relationships (e.g. promotional and educational activities) are more difficult to judge using utilitarian calculus as there is no clear distinction between promotional and educational activities. Many type 3 financial relationships may be permitted using utilitarian calculus if the utility provided by the educational benefits to other surgeons and the financial remuneration of the surgeon outweigh the disutility from the damage to patient trust in the surgical profession in a minority of patients. However, some type 3 financial relationships may also be prohibited if the utility provided by the financial remuneration of the surgeon and education of surgeons about a new product may be outweighed by the disutility caused by the possible encouraged use of devices outside of their clinical indication which may result in
inappropriate treatment and increased costs, and the disutility from the damage to patient trust in the surgical profession.

Type 4 financial relationships (e.g. gifts) may be prohibited as the utility provided by the financial benefit to the surgeon would be outweighed by the disutility from the encouraged use of inferior devices and the damage to patient trust the surgical profession. There is no mitigating condition that could be placed on type 4 financial relationships that could permit these relationships, as a financial limit would decrease the utility of the financial incentive to the surgeon and possible surgeon negligence equally. Therefore, there would be no utility counteracting the disutility from the damage to patient trust.

I expect unease from surgeons regarding my proposal for oversight. However, this mechanism of oversight may ultimately protect appropriate financial relationships between surgeons and manufacturers (i.e. royalties, research consultancy, and educational consultancy). Without adequate oversight, I believe that continued inappropriate financial relationships will occur which may result in further allegations of kickbacks and a degradation of patient trust. Without patient trust, the privilege of professional self-regulation will be removed and legislators will ultimately determine any future relationships between surgeons and manufacturers.

9.2 Future Directions

Future research should examine surgeon opinions on financial relationships between surgeons and manufacturers. Such research could be performed using either qualitative or quantitative methods. Although I believe that qualitative methods would provide more meaningful results, qualitative research is still viewed skeptically by many surgeons. This research would help determine whether surgeons support the idea of professional oversight. I anticipate strong support for my proposed oversight in the academic community, as the interests of academic surgeons would be protected by such oversight. I suspect resistance to oversight among community surgeons, who would face losing value-added perquisites of their relationships with manufacturers (e.g. gifts).
Future research should also examine manufacturer opinion on financial relationships between surgeons and manufacturers. A qualitative study exploring the opinions of the chief executive officers of device manufacturers and device manufacturer representatives would provide manufacturers input into the management of financial relationships between surgeons and device manufactures. Exploration of the views of patients, surgeons and manufacturers would help develop methods of managing financial relationships between surgeons and manufacturers that are endorsed by all involved.

Grounded in rule utilitarianism, I believe that the surgical profession has a moral obligation to promote public trust. In my many conversations with patients regarding financial relationships between health care providers and industry, I have realized that the lay media has the biggest impact in informing the public about these relationships. Unfortunately, media reports uniformly paint the profession in a poor light. The surgical profession should advance public trust by promoting honest articles in the lay media that demonstrate beneficial surgeon-manufacturer collaborations. This would give a more balanced impression of financial relationships that may exist between surgeons and manufacturers, and serve to further enhance the trustworthiness of orthopaedic surgeons and maximize utility.
References


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Appendices

Appendix 1: Qualitative study consent form

Title: Patients’ views on the relationship between orthopaedic surgeons and orthopaedic device manufacturers

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Introduction

You are being asked to take part in a research study. Please read this explanation about the study and its risks and benefits before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish. Participation in this study is voluntary.

Background and Purpose

Little is known about what patients know about companies that make hip and knee replacements (orthopaedic device manufacturers). Patients’ knowledge about the relationship between their orthopaedic surgeon and these companies is also unknown. Other studies have asked patients with cancer about how they feel about their doctors relationship with cancer drug companies but we want to know what patients who have had hip or knee replacements think about these types of relationships. We will be obtaining this information by holding focus groups with patients, like you, who have had hip or knee replacements. By understanding your knowledge, views and perspectives on this relationship we will be able to guide surgeons in how they should interact with the companies and what they tell future patients about their relationships with these companies.
Study Design

Study Visits and Procedures

You are being invited to participate in this study because you have recently had a hip or knee replacement. If you decide to participate you will arrive for your regular follow-up appointment with Dr Gross. After your appointment, you will be directed to the location of the interview. The interview will take approximately 30 minutes. A study coordinator will ask you questions and start discussion. You will be asked to fill out a short questionnaire that will ask some general questions about your age, time since surgery and level of education but will contain no identifiable information. In the interview you will be asked open questions about your knowledge of companies that make hip and knee replacements and what you think are or should be their relationship with surgeons. You may also be asked questions about what information you would like your surgeon to tell you about their relationship with these companies. You can refuse to answer any of the questions and leave the interview at any time. The interview will be recorded with audio tape and later the audiotape will be put into writing. All identifying data will be removed when the audiotape is put into writing. The audiotapes will then be destroyed. Dr Gross will never have access to your statements and these statements will be kept securely following the study and will be destroyed 7 years from the date of the study. After the interview you will have your parking reimbursed for the inconvenience of participating in the study.

Reminders

It is important to remember the following things during this study:

- Ask your study team about anything that worries you about the study or information asked during the focus group.
- Tell your study team if you change your mind about being in this study.

Risks Related to Being in the Study

There are no medical risks if you take part in this study, but being in this study may make you feel uncomfortable. You may refuse to answer questions or stop the interview at any time if there is any discomfort. All information is kept strictly confidential. Your surgeon will never have access to your statements or comments.

Benefits to Being in the Study

You will not receive direct benefit from being in this study. Information learned from this study may help other people undergoing hip and knee replacements in the future.

Voluntary Participation

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may leave the study at any time without affecting your care. You may refuse to answer any question you do not want to answer, or not
answer an interview question by saying “pass”. We will give you new information that is learned during the study that might affect your decision to stay in the study.

Confidentiality

If you agree to join this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your:

- name,
- address,
- date of birth,
- new or existing medical records that includes types, dates and results of medical tests or procedures.

The audiotapes will be destroyed following transcription. The information that is collected for the study will be kept in a locked and secure area by the study doctor for 7 years. It will then be destroyed. Only the study team or the people or groups listed below will be allowed to look at your records. Representatives of the Mount Sinai Hospital Research Ethics Board may look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines.

All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. You will not be named in any reports, publications, or presentations that may come from this study.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission.

In Case You Are Harmed in the Study

If you become ill, injured or harmed as a result of taking part in this study, you will receive care. The reasonable costs of such care will be covered for any injury, illness or harm that is directly a result of being in this study. In no way does signing this consent form waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

Expenses Associated with Participating in the Study

You will be reimbursed $10 for transportation/parking.

Conflict of Interest

The investigators will gain professional benefit from this study through publication in an academic journal. Their interests should not influence your decision to participate in this study. You should not feel pressured to join this study.
Questions about the Study

If you have any questions, concerns or would like to speak to the study team for any reason, please call: Dr Mark Camp at 416-XXX-XXXX or Dr Allan Gross at 416-XXX-XXXX extXXXX.

If you have any questions about your rights as a research participant or have concerns about this study, call Ronald Heslegrave, Ph. D., Chair of the Mount Sinai Hospital Research Ethics Board (REB) or the Research Ethics office number at 416-XXX-XXXX. The REB is a group of people who oversee the ethical conduct of research studies. These people are not part of the study team. Everything that you discuss will be kept confidential.

Consent

This study has been explained to me and any questions I had have been answered.

I know that I may leave the study at any time. I agree to take part in this study.

_________________________ _____________________ ____________________
Print Study Participant’s Name Signature Date
(You will be given a signed copy of this consent form)

My signature means that I have explained the study to the participant named above. I have answered all questions.

_________________________ _____________________ ____________________
Print Name of Person Obtaining Consent Signature Date
Appendix 2: Qualitative study demographic data form

What is your gender? (Please Circle)
   Female
   Male

What is your current age? (Please circle)
   18-39
   40-49
   50-59
   60-69
   70-79
   80 or over

What is your current employment status? (Please circle)
   Working
   Temporarily off work
   Retired

What is your current marital status? (Please circle)
   Single
   Married
   Separated
   Divorced
   Widowed

PLEASE TURN OVER PAGE TO COMPLETE FORM
How many months has it been since your most recent hip or knee replacement?

(Please Circle)

3-6 months
7-12 months
13-24 months (1-2 years)
25-60 months (2-5 years)
61-96 months (5-8 years)
Over 97 months (Over 8 years)

What is the highest level of education you have received?

(Please Circle)

Completed grade school
Some high school
Completed high school
Some college/university
Completed college/university
Graduate/Professional degree
Appendix 3: Qualitative study semi-structured interview guide

“As you know we are interested in what patients’ know about the manufacturers of knee and hip replacements and their relationship with surgeons. Feel free to speak honestly and frankly. There are no right or wrong answers to these questions. We just want to find out your knowledge and learn your opinion.”

What do you know about the companies that make hip and knee replacements?

What do you know about the relationship between the companies and the surgeons?

Do you know anything about the financial relationships between pharmaceutical manufacturers and physicians?

“There are 5 major companies that make hip and knee replacements. Surgeons choose a particular company’s replacements based on many factors including a product’s history and safety data, influence from colleagues and hospital administrators and their own personal preference.”

“Surgeons may have financial relationships with the company that makes hip or knee replacements. Some surgeons get payments because they helped design a replacement or advise the company on how to make improvements based on their expertise.”

What do you feel about surgeons getting paid to help design or improve the hip or knee replacement?

Would you want your surgeon to tell you if they were getting paid for designing or improving a product?

“Surgeons may receive payments because they speak on behalf of the company to other surgeons or educate other surgeons or health professionals to use a company’s product.”

What do you feel about surgeons getting paid for this type of educational activity?
Would you want your surgeon to tell you if they were getting paid for speaking or training on behalf of a company?

“In the past, certain companies have given surgeons gifts, like vacations or money, for using the company’s hip or knee replacements.”

What do you feel about surgeons getting paid these incentives?

Would you want your surgeon to tell you if they were getting paid for using a particular company’s product?

If your surgeon told his or her patients about these financial agreements with the hip and knee replacement companies, how would your attitude towards your surgeon change?

Should it be mandatory for surgeons to tell their patients about any financial relationships that they have with a company before surgery?

How should we ensure that surgeons are not placing their financial interests above the interest of a patient?

If your surgeon was to speak to you about financial relationships, how should they approach it, what specific information should they tell you and how much time should they spend on it?

Is there anything we have not discussed that you would like to talk about?
Appendix 4: Quantitative study patient survey

SURVEY OF PATIENT VIEWS ON FINANCIAL RELATIONSHIPS BETWEEN SURGEONS AND COMPANIES THAT MAKE JOINT REPLACEMENTS

STUDY ID NUMBER: ______________________

DATE OF SURVEY: ______________________

Confidential: No information will be presented or published in a way that would identify an individual.
**Introduction**

Thank you for filling out this survey. We want to find out what you know about companies that make hip and knee replacements and their relationships with surgeons. There is no right or wrong answer to these questions. We just want to find out what you know and learn your opinions. You may not know the answers to some questions and that is okay. You may not have thought about some topics before today, and that is okay too. Just try to answer the questions as best as you can.

We will not give any of your answers to your surgeon or to this hospital. All of your answers will be kept confidential. Filling out this survey will not change the care that you get from your surgeon.

The questions in the survey do not mean that your surgeon has any of the relationships asked about in this survey.

**START OF SURVEY**

1. Below are some statements about your surgeon.

   *For each statement please check the box if you: Strongly Agree, Agree, have No Opinion, Disagree, or Strongly Disagree.*

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>No Opinion</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
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</thead>
<tbody>
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<td></td>
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</tbody>
</table>

   a. Your surgeon is extremely thorough and careful ........................................... □  □  □  □  □

   b. You completely trust your surgeon’s decisions about which surgical treatments are best for you .................. □  □  □  □  □

   c. Your surgeon is totally honest in telling you about all of the different treatment options available for your condition .......... □  □  □  □  □

   d. Sometimes your surgeon cares more about what is convenient for (him/her) than about your medical needs ........... □  □  □  □  □

   e. All in all, you have complete trust in your surgeon ................................................... □  □  □  □  □
Sometimes surgeons can have financial relationships with the companies that make hip and knee replacements. Financial relationships can occur when a doctor or surgeon:

- patents a product and then gets payments because a company uses the product
- provides expertise to help design or improve a product
- gives lectures on behalf of a company
- owns shares in the company
- does research for the company
- gets hotel costs covered by a company at a conference
- gets free textbooks from a company
- gets free meals from a company

2. The statements below describe what you know and how you feel about these financial relationships between companies and surgeons.

For each statement please check the box if you: Strongly Agree, Agree, have No Opinion, Disagree, or Strongly Disagree.

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>No Opinion</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
</table>

a. Before today, you were aware that surgeons could have financial relationships with companies that make hip and knee replacements.......................... ☐ ☐ ☐ ☐ ☐

b. Before today, you were aware that doctors could have financial relationships with drug companies................................. ☐ ☐ ☐ ☐ ☐

c. Before today, you were worried about financial relationships between your surgeon and the company that made your hip or knee replacement.......................... ☐ ☐ ☐ ☐ ☐
3. Think back to when you decided to go ahead with your hip or knee replacement. Imagine that you found out that your surgeon had financial relationships with the company that makes the hip or knee replacement that you were going to be given.

Below is a list of different financial relationships that your surgeon could have had with the company. Choose how appropriate you think each financial relationship is for your surgeon to have had.

_For each statement please check the box if you: Strongly Agree, Agree, have No Opinion, Disagree, or Strongly Disagree._

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>No Opinion</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
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</thead>
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</table>

_It is appropriate for your surgeon to....._

a. Own shares in the company that made your hip or knee replacement......................

b. Get payments from the company for offering advice to the company in your surgeon’s area of expertise..................

c. Get payments from the company to give lectures, including some that might discuss the company’s products.............

d. Get payments from the company for a patent on a product that your surgeon designed..........................................

e. Get gifts worth _more_ than $100 from the company that made your hip or knee replacement................................

f. Get gifts worth _less_ than $100 from the company that made your hip or knee replacement................................

4/12
4. Think back to when you decided to go ahead with your hip or knee replacement. Imagine that you found out that your surgeon had financial relationships with the company that makes the hip or knee replacement that you were going to be given.

Below are statements about possible feelings you could have about these financial relationships.

For each statement please check the box if you: Strongly Agree, Agree, have No Opinion, Disagree, or Strongly Disagree.

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>No Opinion</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
</table>

a. Having financial relationships with the company that made your joint replacement shows that your surgeon is highly qualified.......................... ☐ ☐ ☐ ☐ ☐

b. It is fair for your surgeon to get paid by a company for his/her expertise............... ☐ ☐ ☐ ☐ ☐

c. Your surgeon will make the best choices for your health whether or not he/she has financial relationships with the company that made your joint replacement............ ☐ ☐ ☐ ☐ ☐

d. Having financial relationships with the company that made your joint replacement means that your surgeon may give you a joint replacement that is not the best for you............................. ☐ ☐ ☐ ☐ ☐

e. Having financial relationships with the company that made your joint replacement makes you trust your surgeon's recommendations less............. ☐ ☐ ☐ ☐ ☐
5. **Below are statements about who you think should make sure that financial relationships between your surgeon and a company that makes hip and knee replacements are appropriate.**

*For each statement please check the box if you: Strongly Agree, Agree, have No Opinion, Disagree, or Strongly Disagree.*

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>No Opinion</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
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</tbody>
</table>

a. Your surgeon should make sure these relationships are appropriate.................. □ □ □ □ □

b. A new committee should be created at your surgeon's hospital to make sure these relationships are appropriate........ □ □ □ □ □

c. Your surgeon’s professional organization or Medical Association should make sure these relationships are appropriate........... □ □ □ □ □

d. A new government watchdog should be created to make sure these relationships are appropriate................................. □ □ □ □ □
6. What types of financial relationships would you want your surgeon to tell you before your operation?

*For each statement please check the box if you: Strongly Agree, Agree, have No Opinion, Disagree, or Strongly Disagree.*

<table>
<thead>
<tr>
<th>Your surgeon should TELL you if he/she...</th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>No Opinion</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Owns shares in the company that makes the hip and knee replacements that your surgeon inserts.................................</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>b. Your surgeon gets payments from a company for a patent on a product that your surgeon designed...............................</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>c. Gets payments from a company for helping to design or improve a product based on your surgeon’s expertise............</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>d. Gets payments from a company to give lectures, including some that might discuss the company’s hip or knee replacements.................................</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>e. Gets gifts from a company worth <em>more than $100</em>.................................................................</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
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</tr>
<tr>
<td>f. Gets gifts from a company worth <em>less than $100</em>.................................................................</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
7. Below are statements about why and how your surgeon should tell patients if he or she had financial relationships with the company that made your joint replacement. 

*For each statement please check the box if you: Strongly Agree, Agree, have No Opinion, Disagree, or Strongly Disagree.*

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>No Opinion</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
</table>

a. Knowing your surgeon’s financial relationships would have helped you to make better decisions about your surgery.................................

b. Before surgery, your surgeon should verbally tell you about his/her financial relationships with companies involved in your surgery.................................

c. Before surgery, your surgeon should give you a printed pamphlet telling you about his/her financial relationships with companies.................................

d. Your surgeon should put his/her financial relationships with companies on a public website.................................

e. If your surgeon’s financial relationships were on a public website, you would look at the website before deciding to go ahead with the operation.................................
Question 7 continued.

*For each statement please check the box if you: Strongly Agree, Agree, have No Opinion, Disagree, or Strongly Disagree.*

<table>
<thead>
<tr>
<th></th>
<th>Strongly Agree</th>
<th>Agree</th>
<th>No Opinion</th>
<th>Disagree</th>
<th>Strongly Disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>f. If your surgeon told you about his/her financial relationships (either verbally, by pamphlet or website) you would have more trust in your surgeon than if he or she didn’t tell you.................................</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>g. You would not want to think about these financial relationships before surgery because there are more important risks to think about........................................</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>h. Being told about your surgeon’s financial relationships before surgery would add to your worries..............................................................</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
<tr>
<td>i. You would NOT want to be told about your surgeon’s financial relationships before having surgery.................................</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>
8. We are now going to ask you a question that you have answered already to see if answering this survey has changed your opinion.

For each statement please check the box if you: Strongly Agree, Agree, have No Opinion, Disagree, or Strongly Disagree.

<table>
<thead>
<tr>
<th>Strongly Agree</th>
<th>Agree</th>
<th>No Opinion</th>
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<tbody>
<tr>
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</tbody>
</table>

a. You are worried about financial relationships between YOUR surgeon and the company that made your hip or knee replacement.

☐ ☐ ☐ ☐ ☐

b. You are worried about financial relationships between OTHER surgeons and companies that make hip and knee replacements.

☐ ☐ ☐ ☐ ☐

9. Did your surgeon tell you about his or her financial relationships with the companies that make hip and knee replacements prior to your surgery?

Yes........................................................................................................... ☐

No........................................................................................................... ☐

I can't remember................................................................................... ☐

The questions about your opinions and views are complete.
We would now like to find out a little bit about the people who are answering this survey with the final 7 questions.

10. What is your gender?

Female.................................................................................................... ☐

Male...................................................................................................... ☐

11. In what year were you born?

Year..................................................................................................... 19____
12. What is the highest level of education you have received?

- Completed grade school
- Some high school
- Completed high school
- Some college/university
- Completed college/university
- Graduate/Professional degree
- I don’t know
- I don’t want to answer this question

13. We don’t need to know exactly but before taxes what was your household’s total income in 2009? Include income received from social security or disability payments.

- $25,000 or less
- $25,000-$49,999
- $50,000-$74,999
- $75,000-$99,999
- $100,000 or more
- I don’t know
- I don’t want to answer this question

14. How many joint replacement surgeries have you undergone?

- 1
- 2
- 3
- 4
- 5
- More than 5
15. How long has it been since your most recent joint replacement surgery?

   6 months or less..................................................
   More than 6 months but less than 1 year..................
   More than 1 year but less than 5 years...................
   More than 5 years but less than 10 years..............
   More than 10 years........................................

16. What complications have you had following any joint replacement surgery?

   CHECK ALL THAT APPLY

   No complications................................................
   Infection requiring a second (revision) surgery........
   Fracture requiring a second (revision) surgery........
   Blood Clot......................................................
   A second surgery on the same joint less than 5 years from the first surgery.................................
   Other....................................................................
   Please specify: ...................................................

   I don’t know........................................................
   I don’t want to answer this question........................

THANK YOU FOR COMPLETING THIS SURVEY.
YOUR ANSWERS WILL HELP US IMPROVE OUR PATIENT CARE.

PLEASE HAND YOUR COMPLETED SURVEY BACK TO THE RESEARCH COORDINATOR AND COLLECT YOUR REIMBURSEMENT.
Appendix 5: Quantitative study information letter (New England Baptist Hospital)

Dear Patient

We are inviting you to participate in a research project to study patient views on financial relationships between orthopaedic surgeons and orthopaedic device manufacturers. The research study involves filling out a survey that takes approximately 15 minutes to complete.

What are the reasons for this survey?
The results of this survey will give us an idea about what patients know about financial relationships between orthopaedic surgeons and the companies that make hip and knee replacements. By understanding your knowledge and views, we hope to be able to guide surgeons in how they should interact with the companies and what they should tell future patients about their relationships with these companies.

What does answering this survey involve?
The survey will ask you questions about your knowledge of companies that make hip and knee replacements and what you think are or should be their relationship with surgeons. You will also be asked what information you would like your surgeon to tell you about his or her relationship with these companies.

After you complete the survey, you will hand the survey back to the research coordinator. The survey should take you about 15 minutes to complete. You will receive $10 in cash to reimburse you for the inconvenience of participating and to offset the cost of your parking. The results from this survey will be published in a scientific journal.

What are the risks of completing this survey?
We do not know of any risks to you if you decide to participate in this survey and we guarantee that your responses will be kept strictly confidential. We promise not to share any information that identifies you with anyone outside the research group which consists of Dr David Mattingly (Principal Investigator) and Dr Mark Camp (Research Co-coordinator). The survey does not ask any questions that can be used to identify you.

What are the benefits completing this survey?
You will not receive direct benefit from completing this survey. We hope that information learned from this study may help other people undergoing hip and knee replacements in the future.

Completing this survey is voluntary
Completing this survey is voluntary. You may decide not to complete the survey, or stop the survey at anytime without affecting your care. You may refuse to answer any question you do not want to answer.

By completing the survey you are providing your consent to having your survey answers used in our research study.
Your survey responses will be kept confidential
Your survey responses will be kept in a locked and secure area by the study doctor for 7 years. Only the study team or the people or groups listed below will be allowed to look at your responses. The following people may come to the hospital to look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines:

- Representatives of the study organizing committee.
- New England Baptist Hospital Institutional Review Board.

All information collected during this study will be kept confidential and will not be shared with anyone outside the study unless required by law. The survey does not ask your name, date of birth, address or any information that directly identifies you. You will not be named in any reports, publications, or presentations that may come from this survey. A receipt for the $10 reimbursement with your name on it will be issued and a copy will be kept secure and confidential and will not be shared with anyone outside the study unless required by law.

Questions about the Study
If you have any questions, concerns or would like to speak to the study team for any reason, please call: Dr David Mattingly at 617-XXX-XXXX or Dr Mark Camp at 416-XXX-XXXX.

If you want to speak with someone not directly involved in this research study, or if you have questions or concerns about your rights as a human subject, you can call Dr. Steven Wetzner, Chairperson of the Institutional Review Board (the group that approves studies). He can be reached through the New England Baptist Hospital Office of Research Administration at 617-XXX-XXXX. The Institutional Review Board is not part of the study team. Everything that you discuss will be kept confidential.

Research Study Team at New England Baptist Hospital

Dr David Mattingly
Principal Investigator
Contributing Orthopedic Surgeon

Dr Mark Camp
Study Coordinator

Dr James V. Bono
Contributing Orthopedic Surgeon

Dr Carl Talmo
Contributing Orthopedic Surgeon

Dr Daniel Ward
Contributing Orthopedic Surgeon

Dr Geoffrey Van Flandern
Contributing Orthopedic Surgeon