



Education

Éducation

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Bioethics for clinicians: 17. Conflict of interest in research, education and patient care

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Abstract

A CONFLICT OF INTEREST OCCURS IN A SITUATION in which professional judgement regarding a primary interest, such as research, education or patient care, may be unduly influenced by a secondary interest, such as financial gain or personal prestige. Conflicts of interest exist in every walk of life, including medicine and science. There is nothing inherently unethical in finding oneself in a conflict of interest. Rather, the key questions are whether one recognizes the conflict and how one deals with it. Strategies include disclosing the conflict, establishing a system of review and authorization, and prohibiting the activities that lead to the conflict.

Résumé

IL Y A CONFLIT D'INTÉRÊTS LORSQU'UN INTÉRÊT SECONDAIRE comme le gain financier ou le prestige personnel peut influencer indûment le jugement d'un professionnel au sujet d'un intérêt primordial comme la recherche, l'éducation ou le soin d'un patient. Des conflits d'intérêts surviennent dans toutes les sphères de l'activité humaine, y compris la médecine et les sciences. Il n'y a rien d'intrinsèquement contraire à l'éthique au fait de se retrouver en situation de conflit d'intérêts. Il faut plutôt se demander surtout si l'on reconnaît le conflit et comment on le règle. Les stratégies consistent notamment à divulguer le conflit, à établir un système d'examen et d'autorisation, et à interdire les activités à l'origine du conflit.

Pharmaflux, a drug manufacturer, invites the director of a residency program, Dr. M, to attend a 2-hour session on the treatment of unstable angina at a continuing medical education (CME) event in Banff National Park. The session has been organized by Pharmaflux. Dr. M will receive \$3000, and all her expenses will be paid for a 10-day stay. In exchange, she will have to report her impressions of the 2-hour session during a post-conference dinner retreat in Niagara-on-the-Lake, Ont.

Dr. N did not obtain the federal funding he was counting on for his research project on the efficacy of psychotherapy for the treatment of minor depression. The funding agency to which he applied has experienced significant budget cuts, but Dr. N hopes that more funding will become available and that he will be successful in the next funding cycle in 6 months' time. He is contacted by Rositel, a contract research organization, to work on a randomized clinical trial comparing the efficacy of Luxor, a new drug for the treatment of depression, with that of standard treatment. If he accepts, he will be able to continue to pay the 2 researchers who have worked with him for the past 4 years. He is asked to sign a confidentiality agreement that would prohibit him from disclosing any results of the study without formal approval by the company. Rositel offers \$5000 per patient, to be used at Dr. N's discretion. Dr. N calculates that, after deducting administrative costs, compensation for his researchers, and reasonable compensation to the research subjects and himself for the time spent on the study, there will remain \$2000 per subject recruited. Rositel suggests that he can use this money for personal expenses.



What is a conflict of interest?

A conflict of interest, according to Thompson,¹ “is a set of conditions in which professional judgment concerning a primary interest tends to be unduly influenced by a secondary interest.” In the clinical context the primary obligation of physicians is to their patients, whereas in the research context scientific knowledge may be the primary interest. A secondary interest may be of a financial nature, but it may also consist of personal prestige or academic recognition and promotion. In research involving patients, the research interests, although often in concordance with patients’ interests, are secondary to clinical care and may conflict with it. To some extent, there may even be a conflict of interest if a person is working as a clinician and a researcher at the same time. A secondary interest may be of an altruistic nature, such as the continued employment of the researchers in the second case described above. A typical example of conflict of interest related to personal gain is physician self-referral.² In Thompson’s definition the reference to “a set of conditions” is important — having a conflict of interest is an objective situation and does not depend on underlying motives. Therefore, stating that someone has a conflict of interest does not imply a moral condemnation per se. It is the person’s actions in the context of a particular situation that may be a cause for concern.

Why is conflict of interest important?

Ethics

Physicians who have conflicts of interest risk damaging the trust between them and their patients. Patients rely on physicians’ commitment to patient care. They expect that physicians will not be led by motives other than the pursuit of their patients’ well-being. If a patient perceives that his or her physician is in a conflict-of-interest situation — whether or not the physician is actually influenced by the secondary interest — he or she may lose trust in the physician and in the profession as a whole. Therefore, conflict-of-interest rules safeguard not only the trust of individual patients in their physicians but also the public’s trust in the medical profession.

Secondary interests are sometimes so significant that it is only reasonable to predict that some physicians will be influenced by them. Conflict-of-interest rules recognize the inherent danger of some specific situations. In medicine, they are an expression of the principle that when it comes to patients’ well-being, it is better to err on the side of prudence. This means that public interest warrants general preventive measures, not because *most* physicians

would act inappropriately in such situations, but because it can be predicted that *some will*.

The imbalance of power between physicians and patients adds to the need for a protective framework. Patients are in a vulnerable position and are dependent on the care of their physicians. This is not an ideal situation from which to judge what weight should be given to the potential impact of secondary interests. Their relatively powerless position makes patients inclined to trust their physicians’ decisions. In this context, it seems fair to limit physicians’ freedom to engage in activities that could compromise patient care.

It seems impossible to avoid all negative consequences of conflicts of interest. But as Chren and associates indicate,³ “[p]reserving justice, the trusteeship relationship with our patients, and our own altruism are regulative ideals — that is, standards not always achievable by all of us, but useful templates ‘against which all efforts can be measured.’”³

Law

The law recognizes that fiduciary duties impose limits on the autonomy and freedom of those in a trusteeship position. A fiduciary relationship is one between unequals in which the more powerful party, such as a physician, is entrusted to protect the best interests or well-being of the less powerful party, such as a patient. In fiduciary relationships, conflict-of-interest rules are notably severe. Citing the Supreme Court case *Hodgkinson v. Simms*,⁴ Dickens⁵ argued that people who are in such positions “are required to act conscientiously to avoid conflict between any of their own interests and those of the dependent party they assume or otherwise come under an obligation to protect” and that courts will hold them “to higher duties of protection of dependent parties’ interests.”

Conflict-of-interest rules are also integrated into legislation regulating the health care professions. The 1991 Regulated Health Professions Act of Ontario, for example, contains a Health Professions Procedural Code, on the basis of which specific codes for various regulated health care professions have been established. All of these codes prohibit members of a health care profession from practising the profession “while the member is in a conflict of interest.”⁶ Many of the codes contain specific examples of professional misconduct, such as charging excessive fees and undertaking unnecessary procedures. Although the Ontario regulations governing physicians remain vague as to what exactly constitutes conflict of interest, some conflict-of-interest situations could be dealt with under the provision prohibiting “disgraceful, dishonourable or unprofessional” acts or omissions and “conduct unbecoming a physician.”⁷



In the 1988 case of *Cox v. College of Optometrists of Ontario*⁷ the Divisional Court of the Ontario High Court of Justice ruled that professional organizations have the power to impose stringent regulations dealing with conflict of interest. The court defined a conflict of interest as “a personal interest so connected with professional duty that it might reasonably be apprehended to give rise to a danger of actually influencing the exercise of the professional duty.”⁷ It further ruled that “conflict of interest does not require proof of actual influence by the personal interest upon the professional duty any more than it requires proof of actual receipt of a benefit.”⁷ The court suggested the following test for determining whether the conflict-of-interest rules of a professional organization are within reasonable boundaries: “Can it be said that no reasonable person could conclude that the prohibited private interest could influence the optometrist’s professional conduct?”⁷

Policy

Although there is a traditional body of law on conflict of interest in many other professions, medicine did not start to deal systematically with the issue until the 1980s. Several publications in leading medical journals challenged physicians’ participation in the marketing strategies of pharmaceutical companies and expressed concern for some types of interaction between the industry and the medical profession,^{3,8,9} and several medical organizations and journals established guidelines on conflict of interest.^{9,10} Many medical journals have introduced a requirement that authors disclose any financial interest they have in a study. Some explicitly reject review articles if they are written by people with a financial interest in the review.

In 1990 the American College of Physicians issued a position paper, entitled “Physicians and the pharmaceutical industry,” in which it acknowledged that not only real bias but also perceived bias should be avoided.¹¹ The College recommended, for example, that gifts or subsidies from industry “ought not to be accepted if acceptance might influence or appear to others to influence the objectivity of clinical judgment.” More detailed provisions on gifts and conference subsidies can be found in an opinion of the Council on Ethical and Judicial Affairs, which the American Medical Association (AMA) incorporated into its Code of Medical Ethics.¹² Similar restrictions were introduced by the Canadian Medical Association in 1992; its policy on “Physicians and the pharmaceutical industry,” updated in 1994, covers a variety of interactions with industry.¹³ The policy contains separate sections on research, surveillance studies, continuing medical education and clinical evaluation packages. It emphasizes in its “general principles” that “[t]he primary objective of professional in-

teractions between physicians and industry should be the advancement of health of Canadians rather than the private good of either physicians or industry” and that “[r]elationships with the industry are appropriate only insofar as they do not affect the fiduciary nature of the physician–patient relationship.” The guidelines do not reject industry sponsorship of research and education but suggest strict rules to maintain an arm’s-length relationship between drug manufacturers and physicians. There are many rules, for example, to ensure that CME organizers remain in control of the content of educational events and that any impression of explicit endorsement of a sponsor’s product is avoided. When it comes to industry gifts, the CMA guidelines are stricter than those of the AMA. Whereas the AMA allows gifts of “minimal value,” the CMA stipulates that “physicians should not accept personal gifts from the pharmaceutical industry.” The policy also discourages physicians from investing in drug companies or related undertakings “if knowledge about the success of the company or undertaking might inappropriately affect the manner of their practice or their prescribing behaviour.” The policy further states that “the results of any surveillance study will be made available for publication in a peer-reviewed journal within a reasonable period.”

In 1993 controversy arose after McMaster University’s residency program in internal medicine established more restrictive guidelines, prohibiting lunch briefings by pharmaceutical companies to residents, excluding industry representatives from educational events and rejecting funding when a company insisted on choosing the content of an event.¹⁴ One of the drafters of the guidelines criticized what he perceived as pressure from the industry to soften the guidelines,¹⁵ but others took offence at what they interpreted as a hostile attitude toward industry.^{16,17}

The Pharmaceutical Manufacturers Association of Canada has itself established a Code of Marketing Practices, which is similar to the CMA guidelines and explicitly refers to CMA policy, for example, with respect to education events.¹⁸ The weakness of the enforcement mechanism of the code has recently been exposed, and suggestions have been made to improve the current system.^{19,20}

Empirical studies

Although perception of harm is an important aspect of conflict of interest, and real harm does not have to be proven, it is interesting to see to what extent physicians interact with industry. Lexchin²¹ has provided an excellent overview of the empirical literature between 1978 and 1993. More recently, Hodges²² reported on interactions between industry and psychiatry residents, interns and clerks, and Sergeant and associates²³ surveyed residents in family medicine. Campbell and colleagues²⁴ conducted a



survey to examine the frequency, importance and potential implications of research-related gifts from companies to academic life scientists and found that 43% of respondents had received a gift independent from a grant or contract. These studies indicate that interactions are omnipresent and range from meetings with pharmaceutical detailers, to attending industry-funded educational events, to receiving gifts and promotional items.

But do these interactions influence physicians and medical researchers? As early as 1982, a study by Avorn and colleagues⁸ showed that doctors erroneously believed that their knowledge of 2 popular drugs was based on scientific reports. In reality, their opinion was in line with deceptive advertisements (the published reports indicated that the drugs were not effective for the advertised purposes). Other studies have shown that industry-sponsored education or paid attendance at symposia influences the prescribing patterns of physicians.²¹

Associations have also been shown between the source of funding and the outcome of research studies.²¹ One study compared more than 100 clinical trials and found that trials funded by pharmaceutical firms were less likely to conclude that traditional therapy is better than a new drug.²⁵ Stelfox and collaborators²⁶ recently reviewed articles on the use of calcium-channel antagonists. They found a strong association between financial relations with the pharmaceutical industry, in particular with producers of calcium-channel antagonists, and support for use of the product. The authors concluded that more effective policies on conflict of interest must be developed.²⁶ The survey of Campbell and colleagues²⁴ clearly indicated that most researchers who receive gifts from industry think that industry expects something in return. For example, 32% of recipients reported that the donor expected prepublication review of articles and reports stemming from the use of the gift.²⁴

These findings should not come as a surprise. Industry does not reject the concept that interactions have an impact. For example, a publication for the drug market industry suggested that promotional dinners result in an 80% increase in sales of the promoted drug.²⁷ The clearest indication of the effectiveness of marketing strategies is the amount industry spends on representation and publicity: although the exact amount is a well-kept trade secret, it has been estimated as more than \$5 billion in 1992 in the US²⁸ and \$950 million in Canada.¹⁹

Surprisingly, many physicians continue to believe that they are not likely to be influenced by their interactions with industry. In one survey of the attitudes of internal medicine faculty and residents, a majority agreed that physicians can be compromised by accepting gifts of high monetary value, but few believed that informational services offered by sales representatives had an influence on

their decision-making.²⁹ Interestingly, Hodges²² reported that the more money and promotional items residents had received, the more likely they were to believe that these items had not influenced them. Another study, which compared physicians' receipt of gifts, attitudes toward gifts, attitudes toward advertising, influence of interaction with industry on prescription and assessment of prior training, concluded that physicians who received more gifts were not necessarily more positive about the information provided by industry.³⁰ The authors of that study suggested that physicians are much more discerning than is often thought to be the case. Although the authors concluded that prescribing patterns were not significantly influenced by gifts or other interactions, they did not actually analyse prescribing patterns and physician behaviour. Moreover, patients feel that pharmaceutical gifts are more influential and less appropriate than do their physicians.³¹ Overall, most authors and physicians agree that further educational efforts are required to train physicians in their dealings with industry.^{22,30}

How should I approach conflict of interest in practice?

There is nothing inherently unethical about interactions between physicians and industry. Private sector support can be highly productive for patients by facilitating research progress and the education of health care providers.

Conflict of interest exists in every aspect of human affairs, including medicine and science. Thus there is also nothing inherently unethical in finding oneself in a position of conflict of interest. Serious problems arise, however, if one fails to recognize the conflict and address it appropriately.

The first requirement to deal effectively with conflict of interest is awareness. Physicians must realize not only that they may be influenced but also that public perception of influence may harm trust in clinical care and research. Acknowledging conflict of interest is not a confession of moral failure.³² It is a realistic assessment of the potential impact of secondary interests. Reliance on individual integrity is necessary but not sufficient.¹ Depending on the type of conflict and the potential for real or perceived harm, several strategies are available: disclosure, a system of review and authorization, and prohibition.

Disclosure

Disclosure is the golden rule in conflict of interest. To judge whether one is in a conflict of interest, it can be revealing to ask the question: "Would I feel comfortable if patients and other people found out about my interest in



this matter?" If the answer to this question is "no," then disclosure, at a minimum, is prudent. Although trust can be seriously harmed if patients find out about interests that physicians have hidden, trust is likely to be enhanced if patients feel that their physicians are open about it. Colleagues who attend symposia or read articles should be informed of financial ties between presenters and industry. This simply flags that there could be some conscious or unconscious bias in the study result.

The duty to disclose financial interests is recognized in the practice of many medical journals of publishing the financial interests of authors and in the CMA policy, which states that "[t]he physician should be prepared to disclose the nature of such relationships [with industry] to his or her patient, to the organizers and audience of a continuing medical education (CME) event at which he or she is a speaker, and in comparable situations."¹³

Review and authorization

Disclosure of conflicts is one form of external assessment, but laws and regulations have also introduced formal review systems to control conflict of interest, for example, in the context of medical research. Research ethics boards have a mandate to determine, among other things, whether conflicts of interests are affecting the proper conduct of clinical trials and the health care of patients included in the trials. Laws and regulations logically prescribe that members of review boards should themselves not be in a conflict of interest.³³ University policies often include a system of authorization, under which researchers must report financial interests to the university administration. The administration may then verify whether essential conditions (e.g., no restrictions on publications) are met.³⁴

Prohibition

Disclosure and review and authorization are not always sufficient. Some conflicts of interest may so deeply affect trust that they ought to be prohibited. The CMA policy disapproves, for example, of researchers who are remunerated over and above reasonable compensation for extra work and loss of other income.¹³ Finder's fees, that is, remuneration for merely including research subjects in a clinical trial, ought not to be accepted.³⁵ In that case, the enticement for including subjects without proper informed consent and without respecting selection criteria is too high. The policy further discourages physicians from accepting a fee from industry in exchange for meetings with representatives or for attending promotional activities.¹³ The organizers of CME events are also requested not to "be in a position of conflict of interest by

virtue of any relationship" with companies that fund such events.¹³

The cases

Dr. M has not been invited to make a presentation at the CME event but to report her impressions of the meeting at another leisure event. The prima facie test — "How would people react if I disclose this?" — should suffice to make her reject this proposal. Moreover, the manufacturer is trying to circumvent CMA policy, which provides that "the industry sponsor should not pay for travel or lodging costs or for other personal expenses of physicians attending a CME event."¹³ Mere attendance at and reporting on one session cannot justify this generous offer. Dr. M should also be wary of the fact that the company organized the session. According to CMA policy, the industry sponsors of an event should not decide on the content and the speakers. Every physician must be aware of the potential for conflict in relationships with industry that are too close, but Dr. M has reason to be even more prudent. Her decision-making power and her high profile as director of a residency program give her particular duties with respect to ensuring her independence.

Dr. N's situation represents various levels of conflicting interests. First, scientific interests and industry interests may differ. Dr. N experiences a conflict because research projects that do not involve drug therapy are of less interest to drug manufacturers. Absence of government funding may inappropriately steer research in only one direction. Although industry-sponsored research is important, public health research and non-drug-related research should also be undertaken. This issue is not within Dr. N's control, but it is important that he be aware of it and that he continue to strive for a balanced research portfolio. Second, Dr. N has a legitimate interest in the well-being of his researchers. However, his primary obligations as a physician and a researcher in his own right are toward his patients and toward science. He should only agree to become involved in studies that are of benefit to patients and thus also scientifically valid. Third, as Garfinkel and associates³⁶ indicate, "[i]t is hard to understand why scholars would become involved in research that is not within their control, especially with regard to the use and publication of data." We would even argue that Dr. N's obligations as a medical researcher are irreconcilable with the confidentiality agreement he is asked to sign. Even though some form of confidentiality during and shortly after a trial may be appropriate, for example, for patent protection, agreements to that effect should be carefully drafted so that they respect academic freedom and the obligation to protect research subjects from harm. Investigators ought to preserve the right, and even have an



obligation, to publish the results of a study.¹³ Fourth, Dr. N should not accept finder's fees for including participants in the trial. This might create conscious or unconscious pressure to be flexible with the inclusion criteria and consent procedures.

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