Collaborating with pharmaceutical research
Family physicians beware!

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The Canadian Medical Association (CMA) has recently updated its policy concerning physicians and the pharmaceutical industry.[1] The policy is meant to serve as a guide to physicians, residents, medical students, and medical organizations as they interact with the for-profit health care industry.

In the past, this interaction primarily involved the pharmaceutical industry, but the policy's principles apply to relationships with other commercial organizations, including the information technology industry and manufacturers of health-related products.

The policy first proposes some general principles, then expands on physicians' participation in industry-sponsored research and surveillance studies. It includes a section on the complex (and sometimes controversial) reality of continuing medical education and professional development sponsored by the industry.

While some will criticize this policy as being too restrictive and out of touch with current realities, others will appreciate its emphasis on protecting patient-physician relationships. Some might even find the policy too lenient, but these various views only highlight the historical and current complexity of the collaboration between physicians and industry, collaboration that is unlikely to end soon.

The College of Family Physicians of Canada's Committee on Ethics has developed a work-in-progress for use by those teaching ethics in family medicine training programs. An emphasis on ethics will be supported and formalized in future editions of *Standards for Accreditation of Residency Training Programs*[2] (the "Red Book"). The materials developed by the committee for use in ethics curriculums have been distributed to program directors and can be accessed by any family physician online at **http://www.cfpc.ca/communications/ethics/ethicscurric.asp**. Feedback is encouraged and will guide the committee's future work in this area.

One of the topics included in these resource materials is the interaction between family physicians and the pharmaceutical industry. We have

introduced the topics by way of case presentations, followed by a brief series of questions designed to encourage discussion of relevant principles, policies, and requirements. An example of this format is presented below.

Case presentation

You have been asked to participate in a phase 1 clinical trial sponsored by a pharmaceutical company. The investigation will study the effects of using an old drug in a new way. The disease that the product is thought to treat has no adequate therapy at this time. The research project has been approved by an independent research ethics board. As part of the study, the drug company will give you a computer and purchase high-speed Internet access so you can send your results directly to company headquarters. At the end of the study, you will get to keep the computer, and the company has indicated it will be developing educational software that will be sent to you free of charge.

Questions

1. If you accept the computer but reject the free software, would the arrangement be appropriate?
2. If the company also agrees to provide ongoing Internet access for you following the study, would you accept the offer?
3. Would you feel better about participating if you returned the computer at the end of the study?
4. If the company also offered you a finder's fee of $100 per patient recruited to the study, would you accept it? $500 per patient? $750 per patient?
5. Should your patients be made aware of any agreements you have made with the pharmaceutical company?
6. Are there any guidelines you should follow when participating in medical research?

Discussion

Collaboration with the pharmaceutical industry is a Canadian reality, and family physicians are taking part in research to an ever greater extent. For the most part, this is probably a good thing and could further goals consistent with the four principles of family medicine. As skilled clinicians, family medicine researchers promote the process that results in health care based on the best scientific evidence. As a resource to a practice population, family doctors are committed to lifelong learning and the skilled evaluation of new medical information. These goals can be achieved in a practice setting that includes medical research.

Participating in research, while laudable, can present physicians with practical and philosophical challenges. The patient interaction takes on a new dimension, with new means and ends attached. This can introduce conflicts of interest, some of them serious enough to compromise patient care. Because the danger is real, the CMA's policy has, at its foundation, the notion that a physician's primary obligation is to patients. This means that a physician's interaction with industry should be directed at the advancement of the health of Canadians rather than the private good of either physicians or industry.

Suggested approaches

1. It is probably justifiable to accept the company's computer temporarily if that is the tool that stores and transmits the research information to the main investigators. This is especially true if a participating physician's office has no easily available and suitable alternative. Internet access is also defensible, although some might view this aspect as an enticement to participate, given the likelihood it will be used for purposes other than research.

The software to be provided following the study, presumably in an ongoing fashion, is a "gift," "reward," or unnecessary enticement. Although some industry-promoted educational software is high quality and evidence based, other products have the potential for introducing a biased perspective that might have negative implications for patients.

2. The offer of ongoing high-speed Internet access is an attractive one in light of the wealth of high-quality on-line health care information. Still, it is difficult to justify this offer on the grounds of research necessity and easier to view it as either a gift or substitute for payment (see also answer 4). The CMA's policy clearly advises against accepting personal gifts from industry.
3. Returning the computer would definitely serve to establish clear boundaries and reduce actual or perceived conflicts of interest. Keeping the computer in lieu of getting paid is a possibility, but establishing fair equivalent value might be difficult. One would also have to justify its ongoing presence, long after the research is finished.
4. The CMA's policy strongly promotes the concept that any physician participating in industry-sponsored research is sure that the "activities are ethically defensible,

socially responsible and scientifically valid." Current Canadian standards of evidence used by research ethics boards and individual researchers are contained in the *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans* (**www.sshrc.ca/english/programinfo/policies/ethics.htm**). These standards are predicated on a broad acceptance of the ethical principle of fully informed, competent, and voluntary consent. Physicians are also obliged to protect their patients' privacy. These are matters of both preventing harm and beneficence.

The matter of payment for involvement in research is seen by some to lie sufficiently outside the patient-physician relationship and therefore is of no concern to patients. Even if it could be argued that remuneration does not necessarily constitute enticement, some patients might view payment to physicians as a potential conflict of interest. The CMA has recognized this potential and recommends that patients be informed when their physicians receive a fee for enrolling them in a study. The policy does not strictly prohibit such finder's fees but advises that they should be accepted only if the research activity "exceeds [one's] normal practice pattern." The amount of reimbursement should not exceed an amount equivalent to income lost as a result of participating in a study. Expenditures for extra time, office supplies, and secretarial and nursing support might also be relevant considerations. The details of remuneration should be planned in advance and submitted for approval from an ethics review board.

The question is not simple to answer. An honest assessment of actual time and resource expenditures anticipated as a result of research involvement will be a necessary first step for any physician contemplating acceptance of finder's fees or other remuneration.

5. Generally speaking, patients can provide fully informed consent only when they know all the details surrounding their involvement as research subjects (see also answer 4). They must be able to come to terms with their dual roles: patient and subject, and their doctor's dual role: provider of health care and medical researcher. For some patients, the introduction of financial factors provokes issues of trust, loyalty, and uncertainty. These issues need to be discussed with patients in advance.
6. As mentioned previously, the *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans* is the current Canadian standard with respect to research ethics. This document is lengthy but quite readable. It is a "living document" and as such, has gaps and weaknesses. Future editions will derive from ongoing commentary and debate, but its fundamental principles will likely remain and be transmitted by groups, such as the CMA. As a guide to physicians interacting with industry (in research and in daily practice), the CMA policy[1] is a useful starting point and framework for education, discussion, and debate.

Participating in research is necessary for the advancement of medical science and results in better patient care. Physicians have a duty to their patients and to society that supersedes their obligations to research sponsors. Real and perceived conflicts of interest must be avoided, and patients must remain justifiably convinced that their needs are not being sacrificed for the private good of physicians or the pharmaceutical industry.

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