WMA Statement on Conflict of Interest

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PREAMBLE

This policy is intended to identify areas where a conflict of interest might occur during the day-to-day practice of medicine, and to assist physicians in resolving such conflicts in the best interests of their patients. A conflict of interest is understood to exist when professional judgement concerning direct patient care might be unduly influenced by a secondary interest.

In some cases, it may be enough to acknowledge that a potential or perceived conflict exists. In others, specific steps to resolve the conflict may be required. Some conflicts of interest are inevitable and there is nothing inherently unethical in the occurrence of conflicts of interest in medicine but it is the manner in which they are addressed that is crucial.

In addition to the clinical practice of medicine and direct patient care, physicians have traditionally served in several different roles and pursued various other interests, such as participation in research, the education of future physicians and physicians in training and the occupation of administrative or managerial positions. As private interests within medicine have expanded in many locales, physicians have occasionally provided their expertise to these endeavours as well, acting as consultants (and sometimes employees) for private enterprise.

Although the participation of physicians in many of these activities will ultimately serve the greater public good, the primary obligation of the individual physician continues to be the health and well-being of his or her patients. Other interests must not be allowed to influence clinical decision-making (or even have the potential to do so).

Each doctor has a moral duty to scrutinise his or her own behaviour for potential conflicts of interest, even if the conflicts fall outside the kinds of examples or situations addressed in this document. If unacknowledged, conflicts of interest can

seriously undermine patient trust in the medical profession as well as in the individual practitioner.

Physicians may also wish to avail themselves of additional resources such as specialty societies, national medical associations or regulatory authorities, and should be aware of applicable national regulations and laws.

RECOMMENDATION

Research

The interests of the clinician and the researcher may not be the same. If the same individual is assuming both roles, as is often the case, the potential conflict should be addressed by ensuring that appropriate steps are put in place to protect the patient, including disclosure of the potential conflict to the patient.

As stated in the Declaration of Helsinki:

- The Declaration of Geneva of the World Medical Association states that, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."
- The Declaration of Helsinki states that “In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.”

Research should be conducted primarily for the advancement of medical science. A physician should never place his or her financial interests above the welfare of his or her patient. Patient interests and scientific integrity must be paramount.

All relevant and material physician-researcher relationships and interests must be disclosed to potential research participants, research ethics boards, appropriate regulatory oversight bodies, medical journals, conference participants and the medical centre where the research is conducted.

All hypothesis-testing research trials should be registered with a publicly-accessible research registry.

A clear contract should be signed by all parties, including sponsors, investigators and program participants, clarifying terms relating to, at a minimum:

- financial compensation for the physician-researcher (which should approximate lost clinical earnings)
- ownership of research results (which should rest with the investigator)
- the right of the investigator to publish negative results
- the right of the investigator to release relevant information to trial participants at any point during the study.

Physician-researchers should retain control of and should have full access to all trial data, and should decline non-disclosure clauses.

Physician-researchers should ensure that, regardless of the trial results, the presentation or publication of the results of hypothesis-testing trials will not be unduly delayed or otherwise obstructed.

Referral fees should not be accepted for providing the names of potential trial participants, and patient information should not be released without the consent of the patient, except where required by legislation or regulatory authorities.

Any compensation received from trial sponsors should approximately replace lost clinical income and should be commensurate with the efforts and responsibilities of the physician performing the research. When enrolment is particularly challenging and time-consuming, reasonable additional payments may be made to compensate the clinical investigator or institution specifically for time and effort spent on extra recruiting efforts to enrol appropriate research participants. Escalating bonuses designed to increase trial enrolment should not be accepted.

Physician-researchers should decline requests to review grant applications or research paper submissions from colleagues or competitors where their relationship would have the potential to influence their judgment on the matter.

Payments or compensation of any sort should not be tied to the outcome of clinical trials. Physician-researchers should not have a financial interest in a company sponsoring a trial or a product being studied in a clinical trial if this financial interest could be affected positively or negatively by the results of the trial; they should have

no direct financial stake in the results of the trial. They should not purchase, buy or sell stock (shares) in the company while the trial is ongoing and until the results have been made public. This might not apply for those physicians who have developed a medication but are not part of the enrolment process.

Physician-researchers should only participate in clinical trials when they relate to their area of medical expertise and they should have adequate training in the conduct of research and the principles of research ethics.

Authorship should be determined prior to the start of the trial and should be based on substantive scientific contribution.

Education

The educational needs of students and the quality of their training experience must be balanced with the best interests of patients. Where these are in conflict, the interests of patients will take precedence.

While recognizing that medical trainees require experience with real patients, physician-educators must ensure that these trainees receive supervision commensurate with their level of training.

Patients should be made aware that their medical care may be performed in part by students and physicians in training, including the performance of procedures and surgery, and where possible should give appropriate informed consent to this effect.

Patients should be made aware of the identity and qualifications of the individuals involved in their care.

Refusal by a patient to involve trainees in their care should not affect the amount or quality of care they subsequently receive.

Self-referrals and fee-splitting

All referrals and prescriptions (whether for specific goods or services) should be based on an objective assessment of the quality of the service or of the physician to whom the patient has been referred.

Referral by physicians to health care facilities (such as laboratories) where they do not engage in professional activities but in which they have a financial interest is called self-referral. This practice has the potential to significantly influence clinical decision-making

and is not generally considered acceptable unless there is a need in that particular community for the facility and other ownership is not a possibility (for example, in small rural communities). The physician in this situation should receive no more financial interest than would an ordinary investor.

Kickbacks (or fee-splitting) occur when a physician receives financial consideration for referring a patient to a specific practitioner or for a specific service for which a fee is charged. This practice is not acceptable.

Physician offices

For reasons of patient convenience, many physician offices are located in close geographic proximity to other medical services such as laboratories, pharmacies and opticians. The physician should not receive any financial compensation or other consideration either for referring a patient to these services, or for being located in close geographical proximity to them. Physician-owned buildings should not charge above-market or below-market rates to tenants.

Non-medical products (those having nothing to do with patient health or the practice of medicine) and scientifically non-validated medical products should not be sold out of the physician's office. If scientifically validated medical products are sold out of the physician's office charges should be limited to the costs incurred in making them available and the products should be offered in such a way that the patient does not feel pressured to purchase them.

Organizational/institutional conflicts

Health care institutions in particular are increasingly subject to a number of pressures that threaten several of their roles, and many academic medical centres have begun to identify alternate sources of revenue. Policies should be in place to ensure that these new sources are not in conflict with the values and mission of the institution (for example, tobacco funding in medical schools).

Individual medical organizations and institutions (including, but not limited to, medical schools, hospitals, national medical associations, official/state regulators and research institutions) should develop and, where possible, enforce conflict of interest guidelines for their employees and members.

Physician-researchers and others will benefit from the development of institutional conflict of interest guidelines to assist them in making appropriate disclosure and

clearly identifying situations where a conflict would preclude them from participating in a research study or other activity.

Academic health care institutions should have a clear demarcation between investment decision-making committees, technology transfer and the research arm of the institution.

Written policies should provide guidelines for disclosure requirements, or for discontinuing participation in the decision-making process, for those individuals who are conflicted due to sponsored research, consulting agreements, private holdings or licensing agreements.