

Canadian Orthopaedic Association Code of Ethics

Preamble

In this edition of the Canadian Orthopaedic Code of Ethics we have focused on ethics issues and have minimized what could otherwise be termed Professionalism or Professional Conduct, such issues as being honest and lawful that are assumed to apply to all members of society. Similarly, issues that are basic and more in the realm of Human Rights or law such as discrimination (age, gender, ethnic origin, religion, sexual preference, race, etc...) have been included only where necessary.

The fundamental principle of primacy of patient welfare overrides all others.

This Code of Ethics has specific applications to Canadian culture, society, and the Canadian health care system that may preclude its application elsewhere.

Disclosure

Disclosure is the provision of relevant information. The patient's ability to comprehend the information is referred to as capacity. The patient must be informed about the treatment and its expected effects, relevant alternative option's benefits and risks, and the consequences of declining or delaying treatment. This includes information about any material risks, that is, risks that are common or serious. The surgeon's goal is to disclose information that a reasonable person in the patient's position would need in order to make an informed decision. The patient must be given the opportunity to ask questions and have them answered. There is no acceptable substitute for talking to the patient and assuring comprehension. In emergency situations the extent of disclosure may be less than in the elective situation as the result of the urgency of the situation.

Legal Standards

Particular Person

The Particular Person's Standard of disclosure is the legal standard in Canada. This standard requires that the patient be told what any reasonable person in the same particular circumstances as the patient would want to know in making the decision. This standard includes a consideration of particular details of the patient's life which may impinge upon the appropriateness of the decision.

Reasonable Person

The Reasonable Person's Standard is the legal standard in the United States and was for many years, the legal standard in Canada. It includes disclosing what any reasonable person would want to know in making a decision about the surgery.

Professional Standard

The Professional Standard is the legal standard in the United Kingdom and other jurisdictions is based on what other physicians normally disclose.

Truth Telling

Truth telling involves the provision of information to enable patients to make informed choices about health care and other aspects of their lives and also to inform them about their situation. Patients may have an interest in medical information regardless of whether that information is required to make a decision about medical treatment.

Surgeons will provide information that will have a bearing on medical care decision-making and communicate that information in a way that is comprehensible to the patient. The general rule is that all competent patients should be fully informed. The surgeon should not comply with a request by family or other interested parties to withhold the truth. The patient's right to know is grounded in the ethical principle of autonomy and the inherent trust in the surgeon-patient relationship. If there is any uncertainty or the patient does not ask, the surgeon should provide an opportunity by asking the patient if they wish to know. If the patient wishes to know, he/she must be told. If the patient has requested not to know the surgeon is under no obligation to tell him/her, except perhaps where further investigation or treatment is required and knowing the information is a component of informed consent.

Consent

Surgeons must seek consent before providing diagnostic tests or treatment because capable adults have the right to make informed choices about the health care they receive. This right is grounded in the ethical principle of patient autonomy and the legal doctrine of informed consent.

It includes the right to forego treatments even if this decision results in the patient's death. The elements of consent include: (1) disclosure, (2) capacity, and (3) voluntariness.

- 1) Disclosure: The patient must be provided with relevant information appropriate to his/her personal context.
- 2) Capacity: Can be defined as the ability to understand the consequences of a particular decision. Clinical tools to assist with capacity evaluation are available. A proposed set of questions physicians can use to assess patient capacity include:
 - What is your main medical problem right now?
 - What treatment/diagnostic test has been proposed?
 - What are the risks of having this treatment/diagnostic test?
 - What have you decided about whether or not to have this treatment/diagnostic test, and why have you made this decision?

If there is doubt about the assessment, consultation from a psychiatrist, hospital attorney, or ethicist may be helpful. Psychiatric evaluation is advisable if the surgeon believes that capacity may be compromised by mental illness. In cases of conflict, the ultimate judge of a patient's capacity is court. If the patient is incapable, the physician should seek consent from the appropriate substitute decision maker.

3) Voluntariness: Patients should be able to make treatment choices without undue external coercion.

Consent to Treatment of Incapable Persons

Incompetent patients have the same right to consent as competent patients. In practice, however, incompetent patients cannot exercise this right. To address this paradox, policy makers, judges and legislators have developed a system known as substitute decision making to permit others to exercise the incompetent person's right to consent on his/her behalf.

Substitute decision making poses two main questions: Who should make the decision for the incompetent person and how should the decision be made? The appropriate answer to these questions varies from one jurisdiction to another and physicians are encouraged to gain familiarity with the legal standards in their place of practice. The overall goal of substitute decision making is to approximate the decision the patient would make if he/she were competent to do so.

With regard to who should make decisions, the most appropriate person is someone appointed by the patient him/herself, while competent, through a proxy advance directive. If no such appointment has been made, the most appropriate proxy will be the individual who best knows the patient's prior wishes, if that individual is willing to decide. Other substitute decision makers, in their usual order of priority, include a court-appointed guardian, spouse, child or parent, brother or sister, any other relative or concerned friend. In some jurisdictions, a public official will serve as substitute decision maker for a patient who has no substitute decision maker available. The standards for how the decision should be made, in decreasing order of priority are: wishes, values and beliefs, and best interests. Wishes are prior expressions by the patient, while competent, that seem to apply to the actual decision that needs to be made. Values and beliefs are less specific than wishes but they allow the substitute decision maker to infer what the patient would have decided based on other choices the patient made in his/her life and the patient's approach to life in general. Best interests are an estimation of the benefits and burdens of treatment to the patient.

The preferred answer to both the "who" and "how" questions of substitute decision making is an advance directive. An advance directive is a written document containing a person's wishes about their care. The person makes the advance directive when competent, and the directive takes effect if the person becomes incompetent. The two types of advance directives are *proxy directives*, which names the person who should act as a substitute decision maker, and *instruction directives*, which state what treatments the person would and would not want in various situations. Ideally, proxy and instruction advance directives should be combined.

Consent in Emergencies

A true emergency is an exception to the usual requirement to obtain informed consent. The rationale for this exception is that a reasonable person would normally consent to the treatment and that the delay necessary to obtain consent would have adverse consequences for the patient. This justification is grounded in the ethical principle of beneficence.

In some jurisdictions, the limits of the emergency exception to informed consent have been articulated. If the physician knows that a particular patient would not want treatment in the situation that has arisen then the physician should not provide treatment. The justification for this limit to the emergency exception to the usual requirement for informed consent is that the particular patient's competent refusal of the indicated treatment is well known.

Confidentiality

Respect the patient's right to confidentiality except when this right conflicts with your responsibility to the law, or when the maintenance of confidentiality would result in a significant risk of substantial harm to others or to the patient if the patient is incompetent; in such cases, take all reasonable steps to inform the patient that confidentiality will be breached.

Medical records are confidential documents. Patient authorization is necessary for the disclosure of information contained in such records to a third party, unless such disclosure is required by law. The physician shall not use patient information for any purposes other than for the original intent

Surgical Competence

Competence is possession of the required knowledge, skill, and experience to perform a particular task reliably and produce an appropriate outcome.

Surgeons have an ethical obligation to attain and maintain competence. This obligation derives from our primary ethical obligation, that is, to consider first the well-being of the patient. Surgeons who lack the skills to perform new or unfamiliar procedures should refer their patients to those who have the required skills or seek appropriate training to be able to perform the procedure themselves. Impairment of competence is an issue for surgeons individually and collectively. It may be caused by illness, fatigue, age, physical or emotional stress, alcohol, drugs, or other factors. The surgeon whose competence is impaired or in question should not perform surgical procedures or be involved in patient care.

The surgeon has an obligation to intervene if he/she is aware that a colleague is incompetent whether on the basis of addiction, lack (or loss) of training, skills or knowledge, or if the care provided is below the accepted standard. There must be appropriate grounds for reporting a colleague that are fair, objective and without malice. These concerns should be made to the proper authority and not be expressed to residents, students, or referring physicians. There is

collective responsibility of the surgical community to assure the competence of its members. This should be addressed through peer review.

Surgeons should participate in and comply with programs designed to assess and aid in the maintenance of competence.

Medical Error

Surgeons should disclose the occurrence of adverse events or errors to patients. The disclosure should be accurate and factual and avoid discussion of attribution of responsibility or suggestion that they resulted from negligence (the CMPA can provide assistance in advance of talking to patients and their families about serious error). It should be assumed that the patient would want full disclosure, particularly when harm may occur or when its potential occurrence requires departure from the usual care plan.

Negligent actions should be distinguished from honest mistakes. The former are preventable, harmful errors that result from falling below the standard expected of a reasonably careful and knowledgeable practitioner acting in a similar situation. The admission of error is not an admission of substandard practice. Negligence is a finding made in court and should not be part of a physician's admission of error to a patient.

When practitioners witness errors made by other health care providers, they have an obligation to act on that information. Depending on the circumstances and the magnitude of the error, options range from encouraging disclosure by the erring practitioner to discussing the situation with an appropriate authority (hospital unit director, department chief, risk management, a CMPA representative or a representative from a provincial professional association).

Surgeons must avoid making statements or gestures that could bring on negative or unjust consequences when discussing or making reference to a colleague

Conflict of Interest

Conflict of interest exists in every aspect of human affairs, including medicine and science. There is nothing inherently unethical in finding oneself in a position of conflict of interest, however the conflict must be recognized and managed appropriately.

Professional judgment is trusted by patients and society because of the fiduciary duty doctors accept to rank their primary interest of appropriate patient care above all secondary interests. This duty derives from the covenant of trust and the principle of justice. Justice requires that reasonable expectations should be met, particularly by those who have created the expectation. Doctors profess their intention to serve patients and society in this way. The expectation is that primary interests or purposes will be placed above secondary gains when conflicts arise. Surgeons have an obligation to recognize conflicts of interest, disclose them to the patient and/or public, and resolve any conflict in favor of the patient. Simple disclosure of competing interests is not adequate.

A problem arises when doctors and others do not recognize the seductive interference of secondary gain. A second problem is the perception of interference with primary duties even when no such interference occurs. The custom of accepting favours and financial inducements is more prevalent and accepted in business; it is more prevalent within medicine in some parts of the world than in others. The goal is not to eliminate all conflicts of interest, as they are inextricable from our lives, but to prevent secondary gain from dominating or appearing to dominate professional decisions or choices. If patient care is not compromised by the surgeon's

choice, conflict of interest is not deemed to be present. A surgeon should not directly benefit in ways other than what is considered acceptable and customary (eg fee for service payment or salary payment) from patient care.

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. 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 or unduly influence patient care.

Orthopaedic Surgeon's Relationships with Industry

See Appendix 1: COA Standards of Professionalism in Regard to Conflict of Interest

Research

A study must employ a scientifically valid design to answer the research question. A study must address a question of sufficient value to justify the risk posed to participants. Exposing subjects even to low risk to answer a trivial question is unacceptable. Placebo arms of clinical trials are not acceptable where a standard treatment is known to be of benefit. A study must be conducted in compliance with ethical, institutional and government guidelines. Study findings must be reported accurately and promptly. Methods, results and conclusions must be reported completely and without exaggeration to allow practising clinicians to draw reasonable conclusions.

The demand for scientific rigour introduces changes from everyday therapeutic practice. Researchers who have no clinical responsibility for patients may gain access to their medical records, raising concerns about confidentiality. The requirements of research design might force physician-researchers to accept limitations on the exercise of their clinical judgment. However, the norms that guide ethical research are the principles of respect for autonomy, beneficence, and justice.

The principle of respect for autonomy dictates that potential subjects be given the opportunity to choose whether to participate in research, and their choice should be an informed one. Patients should also understand that their choice not to participate in research will not jeopardize the surgeon-patient relationship nor their ability to receive the standard therapy. Potential conflicts of interest must be declared to the patient and appear in the consent form.

The principle of beneficence imposes on the surgeon an obligation to recommend interventions that, according to the surgeon's judgment, are best for a particular patient. The requirements of good scientific design may take this judgment out of the physician's hands. This occurs most obviously when the alternative treatments are assigned randomly. The response to this argument lies in recognizing how the physician's clinical judgment must be tempered by the opinions of professional colleagues. Professional consensus creates boundaries within which individual clinical judgments may operate.

It is ethical to offer patients participation in a trial only if *clinical equipoise* exists within the expert medical community. *Clinical equipoise* exists when the expert medical opinion remains divided over the best choice among treatment options; The supporters of each alternative realize that the available evidence is inconclusive. The physician who has a decided treatment preference is not obligated to participate in the trial, but should ensure that his or her patients are informed about the differing opinions.

Justice demands that the benefits that may be enjoyed by research participants should be available to all who would willingly participate. It also demands that the potential burdens of participation should be equally shared. Issues of justice should be dealt with when clinical trials are being designed. Those responsible for the design of protocols should ensure that the inclusion and exclusion criteria are justifiable on moral and scientific grounds.

All human research conducted in Canada should receive prior approval by a Research Ethics Board. This arm's length review provides assurance that the potential risks and benefits of the research are understood and within acceptable limits, and that patients' rights are protected. It also adds assurance that the research method is scientifically valid.

Finder's Fees

Finder's Fees are not acceptable. Surgeons act in breach of fiduciary duty and in conflict of interest if they use their professional knowledge of a patient for personal gain. Names may not be given to third parties without patient consent. A surgeon who believes that entry in a study may benefit an eligible patient should inform that patient and let the patient decide whether to participate. Surgeons must not accept a fee based on the number of names provided. If a surgeon is asked to consult patients' records or to do other searches, he or she may be remunerated for the time required to perform that service and for incidental expenses, whether or not any patients are identified and consent to participate.

Resource Allocation

Not all medical goods and services can be supplied to all patients who might want or need them at a time of their convenience. When resources are in short supply so that they are not available to all who might benefit from them, their allocation is referred to as rationing. The appropriate ethical framework from which to approach rationing decisions is justice. The appropriate criteria for distributing health care services are need and benefit. The criteria should be applied using transparently fair procedures. It is unfair to ration based on criteria that may vary from physician to physician. Rationing criteria must be explicit, evenly applied, publicly known, and open to review.

The surgeon has a duty to promote the patient's best interest. The extent of this ethical duty, which is fundamental to the physician's role in resource allocation, is a matter of controversy. Levinsky¹ has argued that "physicians are required to do everything that they believe may benefit each patient without regard to costs or other societal considerations." By contrast, Morreim² has argued that "the physician's obligations to the patient can no longer be a single-minded, unequivocal commitment but rather must reflect a balancing. Patients' interests must be weighed against the legitimate competing claims of other patients, of payers, and of society as a whole, and sometimes even of the physician himself."

¹ Levinsky N.G. The doctor's master. N Engl J Med 1984;311:1573-5.

² Morreim E.H. *Balancing act: the new medical ethics of medicine's new economics*. Washington: Georgetown University Press; 1995:2.

Strategies to deal with rationing include:

- 1. Choose interventions known to be beneficial on the basis of evidence of effectiveness.
- 2. Minimize the use of marginally beneficial tests or treatments.
- 3. Seek the least costly tests or treatments that will accomplish the diagnostic or therapeutic goal; however the patient's best interest must be placed ahead of budgetary concerns.
- 4. Use the natural queue, treating patients in order of appearance unless considerations of need and benefit require modification of this approach.
- 5. Rank patients with whom you have an established patient-doctor relationship ahead of unknown or future patients.
- 6. Support reasonable efforts to conserve health care resources.
- 7. Advocate for your patients, however avoid manipulation of the rules of the health care system to give unfair advantage to your own patients.
- 8. Resolve conflicting claims for scarce resources justly, on the basis of the criteria of need and benefit, using fair and defensible procedures.
- 9. Advocate to resolve unacceptable shortages at the level of hospital management (meso allocation) or through political action at the level of government (macro allocation), rather than at the bedside.
- 10. Inform your patients of the impact of cost constraints on care in a humanistic way. Embittered blaming of administrative or governmental systems during discussions with the patient at the point of treatment should be avoided.
- 11. Develop guidelines for individualization in order to promote a reasonable balance between individual choice and systemic cost control.

Unacceptable criteria for allocation of resources include age, gender, ethnic origin, religion, sexual preference, race, or your belief that that the patient's actions have contributed to their condition.

Blood Borne Infections

Patient positive

- 1. Orthopaedics Surgeons have an obligation to provide necessary treatment to all patients.
- 2. Surgeons should protect themselves by appropriate immunizations and the practice of universal precautions.
- 3. Testing of patients must be voluntary and adequately informed. Appropriate pre-test counseling must be offered.

Surgeon positive

The surgeon should inform the patient of his/her status. Appropriate precautions should be undertaken if surgery is accepted. In emergent situations, positive surgeons may proceed without explicit disclosure and consent when there is no opportunity to provide this information and obtain consent.

End of Life Issues

End of Life Care can be described in three components:

1. Control of pain and other symptoms

No patient should die in pain or with other treatable symptoms. Before social, psychosocial and spiritual problems can be properly addressed, good symptom control must first be achieved.

2. Use of life-sustaining treatments

To the extent possible, the patient and his or her family should be able to choose the site and nature of the care that the patient will receive in the last days of life and should be encouraged to discuss in advance their desires regarding life-sustaining treatments and personal care. Physicians should facilitate this advance care planning and guide and support the patient and the family through the process of giving consent to treatment and arranging for substitute decision-making.

3. Support of patients and their families

The support that each patient and his or her family needs from the physician is unique. The best way to find out what support will be appropriate in a particular situation is to ask, "How can I help you?" Attention to psychosocial issues demands involvement of the patients and their families as partners. An interdisciplinary health care team can help in these areas. Physicians should be sensitive to risk factors for poor adjustment to bereavement and should be knowledgeable about local bereavement services.

Although decisions to forego life-sustaining treatment are legally permissible in Canada, euthanasia and assisted suicide are illegal. Euthanasia can be defined as an action that is intended to lead directly to the death of a patient. Assisted suicide can be defined as the provision of the means, knowledge, or both for euthanasia to a patient, who then uses those means and/or knowledge to commit suicide.

It is easy to distinguish euthanasia and assisted suicide from decisions to forego treatment; euthanasia and assisted suicide involve the injection of a lethal substance or the provision of a lethal overdose, whereas decisions to forego treatment involve the non-initiation or discontinuation of a life-sustaining treatment such as CPR, ventilator, tube feeding, etc. The law permits discontinuation, even though it leads to death, under defined conditions. If the patient and the family do not agree to discontinuation, or if the decision is made on insufficient evidence of irremediable illness, caregivers may be held liable.

When death results from treatment to relieve suffering, legal charges are highly unlikely if the physician's actions meet all of the following three criteria, which represent appropriate palliative care in the eyes of the law:

- 1. There is subjective or objective evidence that the patient is experiencing pain or distress.
- 2. The physician's therapeutic response is commensurate with the level of the patient's pain or distress, and there is evidence of an ongoing feedback loop between the patient's symptoms and signs and the physician's therapeutic response.
- 3. The physician's actions do not represent the direct infliction of death.

Gender Bias

The practice of orthopaedic surgery remains a male dominated specialty. Orthopaedic bodies should strive for appropriate female representation. Orthopaedic surgeons should treat their patients, residents, students, and each other with respect regardless of gender.

Sexual Harassment

An orthopaedic surgeon has an obligation to treat his or her patients and colleagues with respect which precludes harassment and exploitation. Orthopaedic surgeons have an obligation to understand what may be viewed as sexual harassment, both verbal and by action including issues of sexual orientation. An orthopaedic surgeon is obliged to report knowledge of sexual abuse of a patient by a colleague to the provincial College of Physicians and Surgeons.

Glossary

Autonomy: Is the patient's right to make free decisions about his or her health care

Beneficience: The surgeon's obligation to do what's best for the patient

Capacity: In the context of patient consent, capacity refers to the patient's ability to

understand information relevant to a treatment decision and to appreciate the reasonably foreseeable consequences of a decision or

lack of decision.

Clinical Equipoise: Clinical equipoise exists when the expert medical opinion remains

divided over the best choice among treatment options; The supporters of each alternative realize that the available evidence is inconclusive.

Conflict of Interest: A set of conditions in which professional judgment concerning a primary

interest tends to be unduly influenced by a secondary interest.

Disclosure: is the provision of relevant information by the clinician.

Justice: Aristotle's principle of distributive justice states that equals should be

treated equally and those who are unequal should be treated unequally. Unequal treatment is justified when resources are allocated in light of morally relevant differences, such as those pertaining to need or likely

benefit.

Macroallocation: Allocation of resources are made by governments at the national,

provincial and municipal level.

Mesoallocation: Allocation of resources are made at the level of institutions; for example,

hospitals allocate their resources to programs such as cancer treatment,

cardiology and dialysis.

Microallocation: Allocation of resources are made at the level of the individual patient.

Appendix 1

COA Standards of Professionalism in Regard to Conflict of Interest

Professional judgment is trusted by patients and society because of the fiduciary duty doctors accept to rank their primary interest of appropriate patient care above all secondary interests. Innovations including the development of new technology, research and continuing education of orthopaedic surgeons often are supported by industry. It is recognized that this cooperative relationship between orthopaedic surgeons and industry benefits patients. A collaborative relationship between surgeons and industry is necessary, but it must be carefully constructed to avoid conflict of interest whether real or perceived.

Conflict of interest exists when other interests of the physician could influence professional judgment concerning the best interest of the patient. Secondary self-interests of the surgeon may be financial, but also can involve the physician's reputation or time (personal or family).

The guidelines below are the minimum standards of acceptable conduct of orthopaedic surgeons in their relationships with industry.

Orthopaedic Surgeon's Relationships with Industry - Guidelines

- CME accredited educational events: Surgeons and their families should not accept industry funding to attend CME accredited educational events, nor should they accept other associated enticements.
- 2. Non CME approved education and education about new techniques: If wishing to learn a new technique or how to use a new product, surgeons should not accept funding from industry unless the event is endorsed and approved by their local hospital, program, division or department. Only tuition, travel and modest hospitality can be accepted and the focus of the event must be education.
- 3. Faculty at courses/meetings: Support for travel and modest hospitality is appropriate for bone fide faculty. Reasonable honoraria are acceptable. Expenses for accompanying persons should not be included.
- 4. Consultancy: A legal contract that is established in advance is essential. Compensation should be at a level that reflects fair market value and is appropriate for the work done.
- 5. Royalties: If a surgeon receives material benefit from the use of a medical device or product, he or she should not accept payment such as royalties or the like from the use of that product on his or her own patient. It is acceptable to receive royalties or the like when products are used outside the surgeon's home institution.
- 6. Research: Funds involved when collaborating with industry for sound, ethical research (approved by a local peer review and/or ethics committee review of their research protocol) may be acceptable. Finder's fees and related schemes are not acceptable. Questions concerning the propriety of a research arrangement are best dealt with by full disclosure and accessing ethics review board expertise.
- 7. Meeting organization: Financial support from industry for meeting organization is acceptable. Orthopaedic meeting organizers must not be in a position of conflict of interest with the industrial supporters, and must retain control over all aspects of the meeting. The supporters will be acknowledged in printed announcements without reference to specific company products.

8. Resident and fellowship training: There should be no health care industry associated money, gifts (including such items as books, free meals, social events, etc) sponsorship or equivalent accepted directly by individual residents/fellows. Residency/Fellowship Training Programs can receive unrestricted industry grants or support for specific activities as long as there is full, transparent disclosure by the Program of these sources of support through some local processes (on meeting materials, annual reports, website, etc).