Medical Education Systems, Inc.

# Ethics Religion and Medicine

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# Ethics Religion and Medicine

Table of Contents

## Learning Objectives

• Identify and discuss the major issues associated with the debate about whether health professionals may refuse to provide treatments to which they object on moral grounds

• Describe and evaluate the survey presented in this course of physician's attitudes on this issue

• Discuss the roles of religion and the law in formulating a health-care professional's attitudes regarding these issues

• Explain the importance of patients being aware of their physician's views on controversial medical procedures and practices

• Identify and discuss some of the more controversial issues raised in the "cases" section of this course

# Religion, Conscience, and Controversial Clinical Practices


## Abstract

*Background* There is a heated debate about whether health professionals may refuse to provide treatments to which they object on moral grounds. It is important to understand how physicians think about their ethical rights and obligations when such conflicts emerge in clinical practice.

*Methods* We conducted a cross-sectional survey of a stratified, random sample of 2000 practicing U.S. physicians from all specialties by mail. The primary criterion variables were physicians' judgments about their ethical rights and obligations when patients request a legal medical procedure to which the physician objects for religious or moral reasons. These procedures included administering terminal sedation in dying patients, providing abortion for failed contraception, and prescribing birth control to adolescents without parental approval.
(*Farr A. Curlin, M.D., Ryan E. Lawrence, M.Div., Marshall H. Chin, M.D., M.P.H., and John D. Lantos, M.D.)*

*Results* A total of 1144 of 1820 physicians (63%) responded to our survey. On the basis of our results, we estimate that most physicians believe that it is ethically permissible for doctors to explain their moral objections to patients (63%). Most also believe that physicians are obligated to present all options (86%) and to refer the patient to another clinician who does not object to the requested procedure (71%). Physicians who were male, those who were religious, and those who had personal objections to morally controversial clinical practices were less likely to report that doctors must disclose information about or refer patients for medical procedures to which the physician objected on moral grounds (multivariate odds ratios, 0.3 to 0.5).

*Conclusions* Many physicians do not consider themselves obligated to disclose information about or refer patients for legal but morally controversial medical procedures. Patients who want information about and access to such procedures may need to inquire proactively to determine whether their physicians would accommodate such requests.


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Recent controversies regarding physicians and pharmacists who refuse to prescribe or dispense emergency and other contraceptives have sparked a debate about conscientious objection in health care.[1,2,3,4,5] On the one hand, most people believe that health professionals should not have to engage in medical practices about which they have moral qualms. On the other hand, most people also believe that patients should have access to legal treatments, even in situations in which their physicians are troubled about the moral implications of those treatments.[6] Such situations raise a number of questions about the balance of rights and obligations within the doctor–patient relationship. Is it ethical for physicians to describe their objections to patients? Should physicians have the right to refuse to discuss, provide, or refer patients for medical interventions to which they have moral objections?

The medical profession appears to be divided on this issue. Historically, doctors and nurses have not been required to participate in abortions or assist patients in suicide, even where those interventions are legally sanctioned. In recent years, several states have passed laws that shield physicians and other health care providers from adverse consequences for refusing to participate in medical services that would violate their consciences.[7] For example, the Illinois Health Care Right of Conscience Act protects a health care provider from all liability or discrimination that might result as a consequence of "his or her refusal to perform, assist, counsel, suggest, recommend, refer or participate in any way in any particular form of health care service which is contrary to the conscience of such physician or health care personnel."[8] In the wake of recent controversies over emergency contraception, editorials in leading clinical journals have criticized these "conscience clauses" and challenged the idea that physicians may deny legally and medically permitted medical interventions, particularly if their objections are personal and religious. Charo, for example, suggests that the conflict about conscience clauses "represents the latest struggle with regard to religion in America," and she criticizes those medical professionals who would claim "an unfettered right to personal autonomy while holding monopolistic control over a public good."[2] Savulescu takes a stronger stance, arguing that "a doctor's conscience has little place in the delivery of modern medical care" and that "if people are not prepared to offer legally permitted, efficient, and beneficial care to a patient because it conflicts with their values, they should not be doctors."[9]

In spite of such debates, there have been few empirical studies of how physicians think about their responsibilities when their own moral convictions conflict with their patients' requests for legal medical procedures. We examined data from a national survey of U.S. physicians to determine what practicing physicians think their obligations are when a patient requests a legal medical procedure to which the physician has a religious or other moral objection. We quantify the percentage of physicians who might refrain from presenting all treatment options to patients or refuse to refer them to an accommodating provider, and we examine whether particular subgroups of physicians are more likely to do so. We then discuss the implications for ongoing debates concerning the ethics of the doctor–patient relationship.

## Methods

This study's methods have been described in detail elsewhere.[10,11] In 2003, we mailed a confidential, self-administered, 12-page questionnaire (see the Supplementary Appendix, available with the full text of this article at www.nejm.org) to a random sample of 2000 practicing U.S. physicians 65 years of age or younger. The sample was stratified according to specialty. These physicians were chosen from the American Medical Association Physician Masterfile — a database intended to include all physicians in the United States. We included modest oversamples of psychiatrists and physicians who work in several other subspecialties that deal particularly with death and severe suffering, in order to enhance the power of analyses that are not central to this article. Physicians received up to three separate mailings of the questionnaire, and the third mailing offered $20 for participation. The study was approved by the institutional review board of the University of Chicago.

## Questionnaire

The primary criterion variables were physicians' responses to the following three questions: "If a patient requests a legal medical procedure, but the patient's physician objects to the procedure for religious or moral reasons, would it be ethical for the physician to plainly describe to the patient why he or she objects to the requested procedure? Does the physician have an obligation to present all possible options to the patient, including information about obtaining the requested procedure? Does the physician have an obligation to refer the patient to someone who does not object to the requested procedure?" Response categories were yes, no, and undecided.

We also assessed physicians' intrinsic religiosity and religious affiliations. Intrinsic religiosity — the extent to which a person embraces his or her religion as the "master motive" that guides and gives meaning to his or her life[12] — was measured on the basis of agreement or disagreement with two statements: "I try hard to carry my religious beliefs over into all my other dealings in life" and "My whole approach to life is based on my religion." Both statements are derived from Hoge's Intrinsic Religious Motivation Scale[13] and have been validated extensively in previous research.[13,14,15] Intrinsic religiosity was categorized as being low if physicians disagreed with both statements, moderate if they agreed with one but not the other, and high if they agreed with both.

The religious affiliations of the physicians in the survey were categorized as none (a category that included atheist, agnostic, and none), Protestant, Catholic, Jewish, or other (a category that included Buddhist, Hindu, Mormon, Muslim, Eastern Orthodox, and other). Organizational[16] or participatory[17] religiosity was measured according to the frequency of attendance at religious services (never, once a month or less, or twice a month or more).

To determine whether physicians' judgments about their ethical obligations are associated with their views on controversial clinical practices, we asked the survey respondents whether they have a religious or moral objection to terminal sedation (administering sedation that leads to unconsciousness in dying patients), abortion for failed contraception, and the prescription of birth control to adolescents without parental approval. Secondary predictors were the demographic characteristics (age, sex, race or ethnic group, and region) of the physicians surveyed and whether they worked in an academic health center or a religiously oriented or faith-based institution. The primary medical specialty was included as a control variable in the multivariate analyses.

## Statistical Analysis

Weights[18] were assigned and included in the analyses to account for the sampling strategy and the modest differences in response rates according to the respondents' sex and whether they had graduated from a U.S. or foreign medical school. We first generated overall population estimates for agreement with each of the criterion measures. We then used a Mantel–Haenszel test for trend with one degree of freedom (for ordinal predictors) and the chi-square test (for nonordinal predictors) to examine the associations between each predictor and each criterion measure.

Finally, we used multivariate logistic regression to examine whether associations persisted after controlling for other covariates. All reported P values are two-sided and have not been adjusted for multiple statistical testing. All analyses were conducted with Stata SE statistical software (version 9.0).

## Results

Of the 2000 potential respondents, an estimated 9% could not be contacted because their addresses were incorrect or they had died (see the Supplementary Appendix). Among physicians who could be contacted, the response rate was 63% (1144 of 1820). Graduates of foreign medical schools were less likely to respond than graduates of U.S. medical schools (54% vs. 65%, $P<0.001$), and men were less likely to respond than women (61% vs. 67%, $P=0.03$). These differences were accounted for by assigning case weights. The response rates did not differ significantly according to age, region, or board certification. The characteristics of the respondents are listed in Table 1.

**Table 1. Characteristics of the 1144 Survey Respondents and Objections to Controversial Clinical Practices.***

| Characteristic | No./Total No. (%) | Characteristic | No./Tot (% |
|---|---|---|---|
| Female sex | 300/1142 (26) | Religious characteristics | |
| Race or ethnic group† | | Intrinsic religiosity | |
| White, non-Hispanic | 869/1121 (78) | Low | 407/109 |
| Asian | 138/1121 (12) | Moderate | 292/109 |
| Hispanic or Latino | 57/1121 (5) | High | 399/109 |
| Black, non-Hispanic | 26/1121 (2) | Attendance at religious services | |
| Other | 31/1121 (3) | Never | 114/112 |
| Region | | Once a month or less | 499/112 |
| South | 386/1142 (34) | Twice a month or more | 515/112 |
| Midwest | 276/1142 (24) | Religious affiliation | |
| Northeast | 264/1142 (23) | Protestant | 428/112 |
| West | 216/1142 (19) | Catholic | 244/112 |
| Practice in academic medical center | 353/1115 (32) | Jewish | 181/112 |
| Practice in religiously oriented center | 138/1111 (12) | None | 117/112 |
| Primary specialty | | Other | 157/112 |
| Medical and subspecialties | 231/1142 (20) | Opinions about controversial clinical practices | |
| Family practice | 158/1142 (14) | Terminal sedation | |
| Pediatrics and subspecialties | 147/1142 (13) | Do not object | 915/109 |
| General internal medicine | 129/1142 (11) | Object | 182/109 |
| Psychiatry | 100/1142 (9) | Abortion due to failed contraception | |
| Surgery and subspecialties | 100/1142 (9) | Do not object | 527/109 |
| Obstetrics and gynecology | 80/1142 (7) | Object | 564/109 |
| Other | 197/1142 (17) | Prescription of birth control to adolescents without parental consent | |
| | | Do not object | 647/110 |
| | | Object | 461/110 |

* Numbers do not all sum to 1144 because not all respondents answered all the questions. The mean (±SD) age of respondents was
years.
† Race and ethnic group were reported by patients on the survey.

**Table 1.** Characteristics of the 1144 Survey Respondents and Objections to Controversial Clinical Practices.

On the basis of these results, we estimated that when a patient requests a legal medical procedure to which the doctor objects for religious or moral reasons, most physicians believe it is ethically permissible for the doctor to describe that objection to the patient (63%) and that the doctor is obligated to present all options (86%) and to refer the patient to someone who does not object to the requested procedure (71%) (Table 2).

**Table 2. Opinions about the Ethical Obligations of a Physician Who Objects to a Legal Medical Procedure Requested by a Patient.**

| Question and Response | No. (%)* |
|---|---|
| Would it be ethical for the physician to plainly describe to the patient why he or she objects to the requested procedure? | |
| Yes | 715 (63) |
| Undecided | 168 (15) |
| No | 244 (22) |
| Does the physician have an obligation to present all possible options to the patient, including information about obtaining the requested procedure? | |
| Yes | 981 (86) |
| Undecided | 61 (6) |
| No | 86 (8) |
| Does the physician have an obligation to refer the patient to someone who does not object to the requested procedure? | |
| Yes | 820 (71) |
| Undecided | 114 (11) |
| No | 194 (18) |

* Population estimates account for the survey design. Percentages reflect weighted results.

**Table 2.** Opinions about the Ethical Obligations of a Physician Who Objects to a Legal Medical Procedure Requested by a Patient.

Physicians who were more religious (as measured by either their attendance at religious services or their intrinsic religiosity) were more likely to report that doctors may describe their objections to patients, and they were less likely to report that physicians must present all options and refer patients to someone who does not object to the requested procedure (Table 3). As compared with those with no religious affiliation, Catholics and Protestants were more

likely to report that physicians may describe their religious or moral objections and less likely to report that physicians are obligated to refer patients to someone who does not object to the requested procedure.

**Table 3. Opinions about Physicians' Ethical Obligations According to the Religious Characteristics of the Respondents.***

| Religious Characteristic | No. of Respondents (N=1144) | Physicians May Describe Their Moral Objections | | | Physicians Are Obligated to Disclose All Possible Options | | | Physicians Are Obli to Refer the Patie | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | % | P Value | Multivariate Odds Ratio (95% CI) | % | P Value | Multivariate Odds Ratio (95% CI) | % | P Value | M O |
| Intrinsic religiosity | | | 0.001 | | | 0.001 | | | 0.001 | |
| Low† | 405 | 56 | | 1.0 | 92 | | 1.0 | 82 | | 1. |
| Moderate | 290 | 62 | | 1.4 (1.0–2.0) | 84 | | 0.4 (0.2–0.7) | 73 | | 0. |
| High | 397 | 73 | | 2.5 (1.7–3.5) | 81 | | 0.3 (0.2–0.5) | 56 | | 0. |
| Attendance at religious services | | | 0.001 | | | 0.001 | | | 0.001 | |
| Never† | 111 | 51 | | 1.0 | 94 | | 1.0 | 84 | | 1. |
| Once a month or less | 496 | 59 | | 1.5 (0.9–2.4) | 89 | | 0.5 (0.2–1.3) | 79 | | 0. |
| Twice a month or more | 513 | 71 | | 2.7 (1.6–4.3) | 82 | | 0.3 (0.1–0.7) | 60 | | 0. |
| Religious affiliation | | | 0.003 | | | 0.002 | | | 0.001 | |
| Protestant | 427 | 70 | | 2.3 (1.4–3.8) | 86 | | 0.5 (0.2–1.3) | 65 | | 0. |
| Catholic | 243 | 63 | | 1.8 (1.1–3.0) | 79 | | 0.2 (0.1–0.6) | 66 | | 0. |
| Jewish | 179 | 56 | | 1.1 (0.6–1.9) | 93 | | 0.9 (0.3–2.7) | 80 | | 0. |
| None† | 116 | 52 | | 1.0 | 92 | | 1.0 | 88 | | 1. |
| Other | 153 | 63 | | 1.5 (0.8–2.7) | 89 | | 0.4 (0.1–1.2) | 71 | | 0. |

* Population estimates account for the survey design. Percentages reflect weighted results.
† This was the reference category.

**Table 3.** Opinions about Physicians' Ethical Obligations According to the Religious Characteristics of the Respondents.

Physicians who objected to abortion for failed contraception and prescription of birth control for adolescents without parental consent were more likely than those who did not oppose these practices to report that doctors may describe their objections to patients (P<0.001 for both comparisons); the association for the objection to terminal sedation was not significant (P=0.11) (Table 4). Physicians who objected to the three controversial medical practices were less likely to report that doctors must present all options and refer patients to other providers (P<0.001 for all comparisons). The associations for religious characteristics and objections to controversial clinical practices persisted after controlling for age, sex, ethnic group, region, and specialty.

**Table 4. Opinions about Physicians' Ethical Obligations According to Views on Controversial Clinical Practices.***

| View on Controversial Clinical Practice | Respondents (N=1144) | Physicians May Describe Their Moral Objections | | | Physicians Are Obligated to Disclose All Possible Options | | | Physicians Are Obligate the Patient | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | % | P Value | Multivariate Odds Ratio (95% CI) | % | P Value | Multivariate Odds Ratio (95% CI) | % | P Value | M O |
| Terminal sedation | | | 0.11 | | | 0.001 | | | 0.001 | |
| Do not object† | 911 | 62 | | 1.0 | 78 | | 1.0 | 75 | | 1. |
| Object | 182 | 69 | | 1.4 (0.9–2.0) | 89 | | 0.4 (0.2–0.6) | 58 | | 0. |
| Abortion for failed contraception | | | 0.001 | | | 0.001 | | | 0.001 | |
| Do not object† | 524 | 55 | | 1.0 | 91 | | 1.0 | 83 | | 1. |
| Object | 562 | 70 | | 2.0 (1.5–2.7) | 83 | | 0.4 (0.3–0.7) | 60 | | 0. |
| Prescription of birth control to adolescents without parental consent | | | 0.001 | | | 0.001 | | | 0.001 | |
| Do not object† | 646 | 58 | | 1.0 | 92 | | 1.0 | 83 | | 1. |
| Object | 459 | 72 | | 1.6 (1.2–2.2) | 78 | | 0.3 (0.2–0.5) | 71 | | 0. |

* Population estimates account for the survey design. Percentages reflect weighted results.
† This was the reference category.

After adjustment for religious characteristics and other covariates, region, race or ethnic group, practice in an academic medical center, and practice in a religiously oriented health center were not significantly associated with any of the criterion variables. However, with increasing age, physicians were more likely to report that doctors may describe their objections to patients (odds ratio for each additional year of age, 1.02; 95% confidence interval [CI], 1.00 to 1.04). Men were more likely than women to report that physicians may describe their objections (odds ratio, 1.8; 95% CI, 1.3 to 2.5) and less likely to report that physicians are obligated to present all options (odds ratio, 0.5; 95% CI, 0.3 to 0.9) and refer patients to an accommodating provider (odds ratio, 0.5; 95% CI, 0.3 to 0.7).

## Discussion

Most of the physicians in our survey reported that when a patient requests a legal medical intervention to which the physician objects for religious or moral reasons, it is ethically permissible for the physician to describe the reason for the objection but that the physician must also disclose information about the intervention and refer the patient to someone who will provide it. However, the number of physicians who disagreed with or were undecided about these majority opinions was not trivial. If physicians' ideas translate into their practices, then 14% of patients — more than 40 million Americans — may be cared for by physicians who do not believe they are obligated to disclose information about medically available treatments they consider objectionable. In addition, 29% of patients — or nearly 100 million Americans — may be cared for by physicians who do not believe they have an obligation to refer the patient to another provider for such treatments. The proportion of physicians who object to certain treatments is substantial. For example, 52% of the physicians in this study reported objections to abortion for failed contraception, and 42% reported objections to contraception for adolescents without parental consent.

The findings of this study may be important primarily for patients. They should know that many physicians do not believe they are obligated to disclose information about or provide referrals for legal yet controversial treatments. Patients who want full disclosure from their own physicians might inform themselves of possible medical interventions — a task that is not always easy — and might proactively question their physicians about these matters. Patients may not have ready access to information about physicians' religious characteristics and moral convictions. Thus, if patients are concerned about certain interventions for sexual and reproductive health and end-of-life care, they should ask their doctors ahead of time whether they will discuss such options. If a patient wants a treatment that the physician will not provide, the patient may choose to consult a different physician.

Physicians' judgments about their obligations are significantly associated with their own religious characteristics, sex, and beliefs about morally controversial clinical practices. Female physicians are more supportive of full disclosure and referral than are male physicians, perhaps because many controversial issues in medicine (e.g., abortion, contraception, and assisted reproductive technologies) disproportionately involve the sexual and reproductive health of women. Religious physicians are less likely to endorse full disclosure and referral than are nonreligious physicians, perhaps because, as many previous studies have shown, religious physicians are more likely to have personal objections to many controversial medical interventions. Thus, those physicians who are most likely to be asked to act against their consciences are the ones who are most likely to say that physicians should not have to do so.

These conflicts might be understood in the context of perennial debates about medical paternalism and patient autonomy. Strong forms of paternalism are based on the assumption that physicians know what is best for their patients and may therefore make decisions without informing their patients of all the facts, alternatives, or risks. Paternalism is widely criticized for violating the right of adults to self-determination. The inverse of strong paternalism is a strict emphasis on patient autonomy, which suggests that physicians must simply disclose all options and allow patients to choose among them. Models that emphasize patient autonomy to such an extent have been criticized for diminishing the moral agency and responsibility of physicians by making them mere technicians or vendors of health care goods and services.[2,19,20,21,22,23]

This study suggests that the balance that most physicians strike between paternalism and autonomy involves both full disclosure and an open dialogue about the options at hand. This balance resembles the interactive models proposed by Emanuel and Emanuel,[19] Quill and Brody,[20] Siegler,[23] and Thomasma.[21] These ethicists have all recommended models for the doctor–patient relationship that retain the moral agency of both the physician and the patient by encouraging them to engage in a dialogue and negotiate mutually acceptable accommodations that do not require either of the parties to violate their own convictions. In Emanuel and Emanuel's terms, these interactive models retain a role for the influence of "the physician's values, the physician's understanding of the patient's values, [and] his or her judgment of the worth of the patient's values."[19] Although these models require physicians to disclose all information relevant to patients' decisions, they do not require physicians to be value-neutral. Rather, they allow physicians to explain the reasons for their objections to the requested procedures.

The lack of consensus among physicians about whether referrals to other providers who will offer a controversial treatment should be required mirrors the ambivalence about this point within the field of bioethics. Childress and Siegler[22] say that physicians "may" have a duty to inform patients about other physicians who would provide what the patient requests, and Quill and Brody[20] comment that physicians are "perhaps" obligated to facilitate the transfer of care. This ambivalence stems from a long-standing concern that physicians not be asked to act in ways that "would violate [their] personal sense of responsible conduct."[23] Unfortunately, at times the only accommodation that is acceptable to both the patient and the physician may be termination of the clinical relationship.[19,20,22,23]

Our study has several important limitations. Although we did not find substantial evidence of a response bias,[10,11] unmeasured characteristics may have systematically affected physicians' willingness to respond in ways that bias our results. In addition, physicians in different specialties face different arrays of morally controversial practices. Because this study included physicians from all specialties, many participants were asked to report moral judgments about medical practices with which they may have had little or no clinical experience. Moreover, physicians' judgments about their general obligations do not necessarily correspond with their judgments about any particular clinical scenario, and we do not know how their judgments about their obligations translate into their actual practices. Finally, we had three criterion measures and several predictors. Therefore, although hypotheses were theoretically specified and the expected associations were consistently observed, there was the risk of an inflated type 1 error due to multiple comparisons. For all of these reasons, our findings should be considered preliminary, and future studies should use vignettes, patients' reports, or direct observation to measure more directly the ways in which physicians respond to moral conflict in the clinical encounter.

Notwithstanding these limitations, the results of our study suggest that when patients request morally controversial clinical interventions, male physicians and those who are religious will be most likely to express personal objections and least likely to disclose information about the interventions or to refer patients to more accommodating providers. Ongoing debates about conscientious objections in medicine should take account of the complex relationships among sex, religious commitments, and physicians' approaches to morally controversial clinical practices. In the meantime, physicians and patients might engage in a respectful dialogue to anticipate areas of moral disagreement and to negotiate acceptable accommodations before crises develop.

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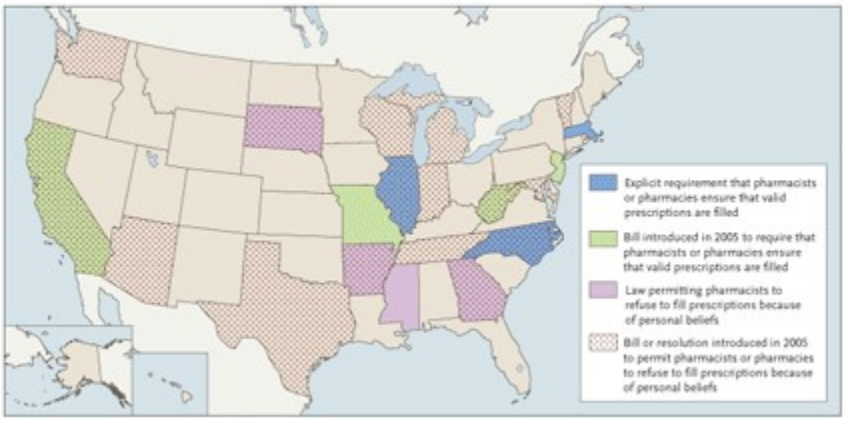
## The Celestial Fire of Conscience — Refusing to Deliver Medical Care

*R. Alta Charo, J.D.* Apparently heeding George Washington's call to "labor to keep alive in your breast that little spark of celestial fire called conscience," physicians, nurses, and pharmacists are increasingly claiming a right to the autonomy not only to refuse to provide services they find objectionable, but even to refuse to refer patients to another provider and, more recently, to inform them of the existence of legal options for care.

Largely as artifacts of the abortion wars, at least 45 states have "conscience clauses" on their books — laws that balance a physician's conscientious objection to performing an abortion with the profession's obligation to afford all patients nondiscriminatory access to services. In most cases, the provision of a referral satisfies one's professional obligations. But in recent years, with the abortion debate increasingly at the center of wider discussions about euthanasia, assisted suicide, reproductive technology, and embryonic stem-cell research, nurses and pharmacists have begun demanding not only the same right of refusal, but also — because even a referral, in their view, makes one complicit in the objectionable act — a much broader freedom to avoid facilitating a patient's choices.




State Requirements Governing the Refusal by Pharmacists to Fill Certain Prescriptions.

Illinois has a regulation that requires pharmacies to fill valid contraception prescriptions in a timely manner, but a resolution has been introduced to permit refusals. Massachusetts has a pharmacy-board policy that requires pharmacists to fill valid prescriptions in a timely manner. North Carolina has a pharmacy-board policy that requires pharmacists to ensure that valid prescriptions are filled in a timely manner. Wyoming has a bill that would permit providers to refuse to abide by advance directives that might, in some scenarios, apply to pharmacists who refuse to fill certain prescriptions. Adapted from a map compiled by the National Women's Law Center.

A bill recently introduced in the Wisconsin legislature, for example, would permit health care professionals to abstain from "participating" in any number of activities, with "participating" defined broadly enough to include counseling patients about their choices. The privilege of abstaining from counseling or referring would extend to such situations as emergency contraception for rape victims, in vitro fertilization for infertile couples, patients' requests that painful and futile treatments be withheld or withdrawn, and therapies developed with the use of fetal tissue or embryonic stem cells. This last provision could mean, for example, that pediatricians — without professional penalty or threat of malpractice claims — could refuse to tell parents about the availability of varicella vaccine for their children, because it was developed with the use of tissue from aborted fetuses.

This expanded notion of complicity comports well with other public policy precedents, such as bans on federal funding for embryo research or abortion services, in which taxpayers claim a right to avoid supporting objectionable practices. In the debate on conscience clauses, some professionals are now arguing that the right to practice their religion requires that they not be made complicit in any practice to which they object on religious grounds.

Although it may be that, as Mahatma Gandhi said, "in matters of conscience, the law of majority has no place," acts of conscience are usually accompanied by a willingness to pay some price. Martin Luther King, Jr., argued, "An individual who breaks a law that conscience tells him is unjust, and who willingly accepts the penalty of imprisonment in order to arouse the conscience of the community over its injustice, is in reality expressing the highest respect for law."

What differentiates the latest round of battles about conscience clauses from those fought by Gandhi and King is the claim of entitlement to what newspaper columnist Ellen Goodman has called "conscience without consequence."

And of course, the professionals involved seek to protect only themselves from the consequences of their actions — not their patients. In Wisconsin, a pharmacist refused to fill an emergency-contraception prescription for a rape victim; as a result, she became pregnant and subsequently had to seek an abortion. In another Wisconsin case, a pharmacist who views hormonal contraception as a form of abortion refused not only to fill a prescription for birth-control pills but also to return the prescription or transfer it to another pharmacy. The patient, unable to take her pills on time, spent the next month dependent on less effective contraception. Under Wisconsin's proposed law, such behavior by a pharmacist would be entirely legal and acceptable. And this trend is not limited to pharmacists and physicians; in Illinois, an emergency medical technician refused to take a woman to an abortion clinic, claiming that her own Christian beliefs prevented her from transporting the patient for an elective abortion.

At the heart of this growing trend are several intersecting forces. One is the emerging norm of patient autonomy, which has contributed to the erosion of the professional stature of medicine. Insofar as they are reduced to mere purveyors of medical technology, doctors no longer have extraordinary privileges, and so their notions of extraordinary duty — house calls, midnight duties, and charity care — deteriorate as well. In addition, an emphasis on mutual responsibilities has been gradually supplanted by an emphasis on individual rights. With

autonomy and rights as the preeminent social values comes a devaluing of relationships and a diminution of the difference between our personal lives and our professional duties.

Finally, there is the awesome scale and scope of the abortion wars. In the absence of legislative options for outright prohibition, abortion opponents search for proxy wars, using debates on research involving human embryos, the donation of organs from anencephalic neonates, and the right of persons in a persistent vegetative state to die as opportunities to rehearse arguments on the value of biologic but nonsentient human existence. Conscience clauses represent but another battle in these so-called culture wars.

Most profoundly, however, the surge in legislative activity surrounding conscience clauses represents the latest struggle with regard to religion in America. Should the public square be a place for the unfettered expression of religious beliefs, even when such expression creates an oppressive atmosphere for minority groups? Or should it be a place for religious expression only if and when that does not in any way impinge on minority beliefs and practices? This debate has been played out with respect to blue laws, school prayer, Christmas crèche scenes, and workplace dress codes.

Until recently, it was accepted that the public square in this country would be dominated by Christianity. This long-standing religious presence has made atheists, agnostics, and members of minority religions view themselves as oppressed, but recent efforts to purge the public square of religion have left conservative Christians also feeling subjugated and suppressed. In this culture war, both sides claim the mantle of victimhood — which is why health care professionals can claim the right of conscience as necessary to the nondiscriminatory practice of their religion, even as frustrated patients view conscience clauses as legalizing discrimination against them when they practice their own religion.

For health care professionals, the question becomes: What does it mean to be a professional in the United States? Does professionalism include the rather old-fashioned notion of putting others before oneself? Should professionals avoid exploiting their positions to pursue an agenda separate from that of their profession? And perhaps most crucial, to what extent do professionals have a collective duty to ensure that their profession provides nondiscriminatory access to all professional services?

Some health care providers would counter that they distinguish between medical care and nonmedical care that uses medical services. In this way, they justify their willingness to bind the wounds of the criminal before sending him back to the street or to set the bones of a battering husband that were broken when he struck his wife. Birth control, abortion, and in vitro fertilization, they say, are lifestyle choices, not treatments for diseases.

And it is here that licensing systems complicate the equation: such a claim would be easier to make if the states did not give these professionals the exclusive right to offer such services. By granting a monopoly, they turn the profession into a kind of public utility, obligated to provide service to all who seek it. Claiming an unfettered right to personal autonomy while holding monopolistic control over a public good constitutes an abuse of the public trust — all the worse if it is not in fact a personal act of conscience but, rather, an attempt at cultural conquest.

Accepting a collective obligation does not mean that all members of the profession are forced to violate their own consciences. It does, however, necessitate ensuring that a genuine system for counseling and referring patients is in place, so that every patient can act according to his or her own conscience just as readily as the professional can. This goal is not simple to achieve, but it does represent the best effort to accommodate everyone and is the approach taken by virtually all the major medical, nursing, and pharmacy societies. It is also the approach taken by the governor of Illinois, who is imposing an obligation on pharmacies, rather than on individual pharmacists, to ensure access to services for all patients.

Conscience is a tricky business. Some interpret its personal beacon as the guide to universal truth. But the assumption that one's own conscience is the conscience of the world is fraught with dangers. As C.S. Lewis wrote, "Of all tyrannies, a tyranny sincerely exercised for the good of its victims may be the most oppressive. It would be better to live under robber barons than under omnipotent moral busybodies. The robber baron's cruelty may sometimes sleep, his cupidity may at some point be satiated; but those who torment us for our own good will torment us without end for they do so with the approval of their own conscience."

## Conscientious objection in medicine

http://www.bmj.com/cgi/content/full/332/7536/294

Shakespeare wrote that "Conscience is but a word cowards use, devised at first to keep the strong in awe" (*Richard III* V.iv.1.7). Conscience, indeed, can be an excuse for vice or invoked to avoid doing one's duty. When the duty is a true duty, conscientious objection is wrong and immoral. When there is a grave duty, it should be illegal. A doctors' conscience has little place in the delivery of modern medical care. What should be provided to patients is defined by the law and consideration of the just distribution of finite medical resources, which requires a reasonable conception of the patient's good and the patient's informed desires (box). If people are not prepared to offer legally permitted, efficient, and beneficial care to a patient because it conflicts with their values, they should not be doctors. Doctors should not offer partial medical services or partially discharge their obligations to care for their patients.

**Problem of conscientious objection**

Doctors have always given a special place to their own values in the delivery of health care. They have always had greater knowledge of the effects of medical treatment, and this fostered a belief that they should decide which treatments are appropriate for patients— that is, paternalism. Their values crept into clinical decisions.[1,2] This has been squarely overturned by greater patient participation in decision-making and the importance given to respecting patients' autonomy.[3] More recently, doctors' values have reappeared as a right to conscientiously object to offering certain medical services. Examples include, refusal to offer termination of pregnancy, especially late term termination, to women who are legally entitled to it and refusal to provide reproductive advice and help to gay couples, single women, or others deemed socially unacceptable.

In the United States pressure has been put on Catholic hospitals to allow obstetricians to sterilize women immediately after giving birth.[4] Alto Charo notes that a recently proposed Wisconsin bill would allow doctors to refrain from a broad range of activities, including counseling patients:

The privilege of abstaining from counseling or referring would extend to such situations as emergency contraception for rape victims, in vitro fertilization for infertile couples, patients' requests that painful and futile treatments be withheld or withdrawn, and therapies developed with the use of fetal tissue or embryonic stem cells. This last provision could mean, for example, that pediatricians... could refuse to tell parents about the availability of varicella vaccine for their children, because it was developed with the use of tissue from aborted fetuses.[5]

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|---|
| Determinants of medical care<br>**Law**<br><br>Just distribution of finite resources Patient's informed desires<br><br>**Not doctors' values** |

Indeed, one Wisconsin pharmacist refused to fill an emergency contraception prescription for a rape victim. She became pregnant and had an abortion.[5]

**Arguments against conscientious objection**

**Inefficiency and Inequity**

In public medicine, conscientious objection introduces inequity and inefficiency. In a survey I conducted several years ago,[6] around 80% of clinical geneticists and obstetricians specializing in ultrasonography believed termination of pregnancy should be available for a normal 13 week pregnancy if the woman wants it for career reasons. However, only about 40% were prepared to facilitate it. This implied that less than half of doctors whose primary job is to deal with termination of pregnancy would facilitate a termination at 13 weeks if the woman wanted it for career reasons. The service that patients receive depends on the values of the treating doctor. Not only does this imply that patients must shop among doctors to receive the service to which they are entitled, introducing inefficiency and wasting resources, it also means some patients, less informed of their entitlements, will fail to receive a service they should have received. This inequity is unjustifiable.

**Inconsistency**

Imagine an intensive care doctor refusing to treat people over the age of 70 because he believes such patients have had a fair innings. This is a plausible moral view,[7] but it would be inappropriate for him to conscientiously object to delivering such services if society has deemed patients are entitled to treatment.

Or imagine in an epidemic of bird flu or other infectious disease that a specialist decided she valued her own life more than her duty to treat her patients. Such a set of values would be incompatible with being a doctor.

If there is any justification for compromising the care of patients, it must be a grave risk to a doctor's physical welfare. But if self-interest and self-preservation are not generally deemed sufficient grounds for conscientious objection, how can religious or other values be?

**Commitments of a Doctor**

These examples show that people have to take on certain commitments in order to become a doctor. They are a part of being a doctor. Someone not prepared on religious grounds to do internal examinations of women should not become a gynecologist. To be a doctor is to be willing and able to offer appropriate medical interventions that are legal, beneficial, desired by the patient, and a part of a just healthcare system.

If we do not allow moral values or self-interest to corrupt the delivery of the just and legal delivery of health services, we should not let other values, such as religious values, corrupt them either.

**Discrimination**

Sometimes religious values are considered special. However, to treat religious values differently from secular moral values is to discriminate unfairly against the secular, a practice not uncommon in medical ethics.[8] Other values can be as closely held and as central to conceptions of the good life as religious values.

**Place for conscientious objection**

The argument in favor of allowing conscientious objection is that to fail to do so harms the doctor and constrains liberty. This is true. When a doctor's values can be accommodated without compromising the quality and efficiency of public medicine they should, of course, be accommodated. If many doctors are prepared to perform a procedure and known to be so, there is an argument for allowing a few to object out. A few obstetricians refusing to perform abortions may be tolerable if many others are prepared to perform these, just as a few self-interested infectious disease doctors refusing to treat patients in a flu epidemic, on the grounds of self interest, might be tolerable if there were enough altruistic physicians willing to risk their health. But when conscientious objection compromises the quality, efficiency, or equitable delivery of a service, it should not be tolerated. The primary goal of a health service is to protect the health of its recipients.

Certain constraints are necessary to ensure the legal, equitable, and efficient delivery of health care:

- Medical students and trainees must be aware of the commitments of the profession and be prepared to undertake these or not become doctors

- The medical profession has an obligation to ensure that all patients are aware of the full range of services to which they are entitled

- Any would-be conscientious objector must ensure that patients know about and receive care that they are entitled to from another professional in a timely manner that does not compromise their access to care

- Doctors who compromise the delivery of medical services to patients on conscience grounds must be punished through removal of license

- The place for expression and consideration of different values is at the level of policy relating to public medicine.

**Legal Uncertainty**

In some areas of medicine, such as the hastening of death and late termination of pregnancy, doctors may in good faith be uncertain as to whether an intervention is legal. In 1990, the Human Fertilization and Embryology Act in the United Kingdom reduced the limit for "social termination" to 24 weeks, but placed no upper gestational limit on termination when there is "substantial risk of serious handicap" or if it is necessary to prevent "grave permanent injury to the physical or mental health of the pregnant woman." Concern has been expressed about what constitutes a substantial risk and a serious handicap. Milford and Thornton claimed that the issue might cause significant public controversy and expressed their "deep personal uncertainty."[9] In 1993, Green asked 391 obstetric consultants in the United Kingdom how late they would be prepared to offer termination of pregnancy for anencephaly, spina bifida, and Down's syndrome.[10] She found that 89% of consultants would offer termination for anencephaly at 24 weeks, falling to 64% beyond 24 weeks. For Down's syndrome, 60% would offer termination at 24 weeks but only 13% after this time. For open spina bifida, 53% would offer termination at 24 weeks and 21% after 24 weeks.

**Summary points**

A doctor's conscience should not be allowed to interfere with medical care

All doctors and medical students should be aware of their responsibility to provide all legal and beneficial care

Conscientious objection may be permissible if sufficient doctors are willing to provide the service

Conscientious objectors must ensure that their patients are aware of the care they are entitled to and refer them to another professional

Conscientious objectors who compromise the care of their patients must be disciplined

Australia, laws relating to late termination are even more unclear and vary from state to state.[6 11] My survey of clinical geneticists and obstetricians with specialist training in obstetric ultrasonography showed similar variation in practice to that found by Green.[6] I asked respondents to imagine that a pregnant woman presents after prenatal testing with one of several diagnoses at 13 and 24 weeks. These included anencephaly, trisomy 18, hypoplastic left heart, spina bifida with hydrocephalus, fragile X syndrome, Down's syndrome, achondroplasia, and cleft palate. I also asked respondents about pregnancies in which the fetus was normal.

Some practitioners would not facilitate termination at 24 weeks even for lethal abnormalities. Fewer practitioners supported termination or would facilitate it at 24 weeks than at 13 weeks for all conditions. The difference in opinion between 24 and 13 weeks was greatest for pregnancies in which the fetus was normal or had a relatively mild disorder. There was a lack of consensus about which abnormalities were severe enough to warrant termination and up to what gestation termination is acceptable. For example, around 75% of respondents believed termination should be available for dwarfism at 24 weeks.

Such wide variation in practice around late termination is due both to practitioners' differing values but also to legitimate uncertainty about the legal status of late termination for "milder" conditions. I have argued elsewhere that we urgently need to clarify the law in this area.[11] In the absence of such clarification, practitioners have a legitimate right to refuse to provide a service which they believe to be illegal. However, they should make this reason clear to patients and also the fact that the law is unclear. They should also inform patients of the availability of other practitioners who take a different view of the law.

**Private elective medicine**

Private elective medicine is different from public medicine. Doctors have more liberty to offer the service of their choice, based on their values. Nevertheless, for patients to give valid consent to treatment, they must be informed of relevant alternatives and their risks and benefits (in a reasonable, complete, and unbiased way).

**Conclusion**

Values are important parts of our lives. But values and conscience have different roles in public and private life. They should influence discussion on what kind of health system to deliver. But they should not influence the care an individual doctor offers to his or her patient. The door to "value-driven medicine" is a door to a Pandora's box of idiosyncratic, bigoted, discriminatory medicine. Public servants must act in the public interest, not their own.

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# Bioethics for clinicians

The following series of essays is intended to elucidate key concepts in bioethics and to help clinicians to integrate bioethical knowledge into daily practice.

## Consent

**Abstract**
Patients are entitled to make decisions about their medical care and to be given relevant information on which to base such decisions. The physician's obligation to obtain the patient's consent to treatment is grounded in the ethical principles of patient autonomy and respect for persons and is affirmed by Canadian law and professional policy. A large body of research supports the view that the process of obtaining consent can improve patient satisfaction and compliance and, ultimately, health outcomes. An exception to the requirement to obtain consent is the emergency treatment of incapable persons, provided there is no reason to believe that the treatment would be contrary to the person's wishes if he or she were capable.

### Introduction

Mr. A is an 85-year-old man living at home with his wife, who has moderately severe Alzheimer disease and for whom he provides daily care. He has an 8.5-centimetre abdominal aortic aneurysm. Three months ago he consulted a vascular surgeon, who recommended surgical repair of his aneurysm. However, another physician told Mr. A that he "would never survive the operation." Mr. A decided to "take his chances" and refused surgery, primarily because of his wish to provide uninterrupted care for his wife; however, he agreed to discuss the decision further with the surgeon at a future visit. Before such a visit takes place, however, Mr. A is taken to the emergency department after collapsing at home with abdominal pain. Physical examination reveals a systolic blood pressure of 50 mm Hg and a tender pulsatile abdominal mass. Mr. A is moaning and barely conscious. The surgeon diagnoses a ruptured aortic aneurysm and believes that Mr. A will die without emergency surgery. No relatives can be reached for consultation.

Mr. B, a 69-year-old resident of a nursing home, has severe Alzheimer disease. He is dependent on others to carry out all activities of daily living and is incontinent of urine and feces. He does not recognize his family members, and his speech is limited to moaning and crying. He has had fever, a cough producing green sputum and shortness of breath for 48 hours. He is transferred to hospital for treatment of suspected pneumonia. His wishes regarding treatment for pneumonia have not been documented. The nursing home has already notified Mr. B's wife, who is now driving to the hospital and will arrive in about 30 minutes.

**What is consent?**

Consent is the "autonomous authorization of a medical intervention . . . by individual patients."[1] Patients are entitled to make decisions about their medical care and have the right to be given all available information relevant to such decisions. Obtaining consent is not a discrete event; rather, it is a process that should occur throughout the relationship between clinician and patient.[2] Although the term "consent" implies acceptance of treatment, the concept of consent applies equally to refusal of treatment. Patients have the right to refuse treatment and to be given all available information relevant to the refusal.

Consent has three components: disclosure, capacity and voluntariness. "Disclosure" refers to the provision of relevant information by the clinician and its comprehension by the patient. "Capacity" refers to the patient's ability to understand the relevant information and to appreciate those consequences of his or her decision that might reasonably be foreseen. "Voluntariness" refers to the patient's right to come to a decision freely, without force, coercion or manipulation.

Consent may be explicit or implied.[3] Explicit consent can be given orally or in writing. Consent is implied when the patient indicates a willingness to undergo a certain procedure or treatment by his or her behavior. For example, consent for venipuncture is implied by the action of rolling up one's sleeve and presenting one's arm. For treatments that entail risk or involve more than mild discomfort, explicit rather than implied consent should be obtained.

Signed consent forms document but cannot replace the consent process. There are no fixed rules as to when a signed consent form is required. Some hospitals require that a consent form be signed by the patient for surgical procedures but not for certain equally risky interventions. If a signed consent form is not required, and the treatment carries risk, clinicians should seriously consider writing a note in the patient's chart to document that the consent process has occurred.

In this article we will discuss the concept of patient consent and exceptions to the requirement to obtain consent. Subsequent articles in this series will provide a detailed discussion of disclosure, capacity and voluntariness, as well as requirements for patient consent to participation in medical research.

**Why is consent important?**

**Ethics**

The notion of consent is grounded in the ethical principles of patient autonomy and respect for persons. "Autonomy" refers to the patient's right to make free decisions about his or her health care. Respect for persons requires that health care professionals refrain from carrying out unwanted interventions and that they foster patients' control over their own lives.

**Law**

Obtaining the patient's consent to medical care is a legal requirement. Under common law, treating a patient without his or her consent constitutes battery,[4] whereas treating a patient on the basis of inadequately informed consent constitutes negligence.[5] Ontario's Health Care

Consent Act (1996) defines the elements of consent, describes how capacity should be determined, allows patients to challenge a finding of incapacity and defines who may give consent on behalf of the patient.[6] British Columbia[7] and Prince Edward Island[8] are in the process of enacting similar legislation.

### Policy

The requirement to obtain patient consent is affirmed by professional organizations such as the Royal College of Physicians and Surgeons of Canada, the Canadian Council on Hospital Accreditation and the CMA. For example, the CMA's policy summary on informed decision-making states:

Obtaining valid consent before carrying out medical, therapeutic and diagnostic procedures has long been recognized as an elementary step in fulfilling the doctor's obligations to the patient.[9]

### Empirical studies

Several meta-analyses and reviews have suggested that the process of obtaining consent can be an important component of a successful physician-patient relationship. One review found that effective physician-patient communication improved emotional health, symptom resolution, level of function, results of physiologic measures and pain control.[10] A meta-analysis showed that providing information about what the patient would feel and what would be done in the course of stressful and painful medical procedures consistently reduced negative feelings, pain and distress.[11] Another demonstrated that information-giving by physicians was associated with small to moderate increases in patient satisfaction and compliance with treatment.[12]

## How should I approach the consent process in practice?

### Problem solving and decision making

Clinicians often struggle with the question of how to apply the ethical and legal concept of consent in their daily practice. It is helpful to distinguish the process of problem solving from that of decision making.[13] Problem solving involves identifying the patient's presenting problem and developing a list of treatment options. Most patients expect the physician to assume the role of problem solver.[14,15] Decision-making involves choosing from the treatment options. Several studies have shown that patients' desire for decision-making responsibility is variable.[16-23] Even patients who actively seek information do not necessarily wish to make the decision about which treatment option to follow.[24,25] Some, particularly those who are elderly or acutely ill, are predisposed to follow the physician's recommendation.[26-28]

Obtaining valid consent requires that patients participate in problem solving as much as they wish. Patients should be free to ask questions and receive answers about treatment options not discussed by the clinician. The consent process also requires that patients actively participate in decision-making and authorize the decision. Even if the patient is predisposed to follow the

clinician's recommendation, the clinician should actively engage the patient in the consent process.

**Exceptions**

Common law recognizes that the emergency treatment of incapable persons is an exception to the requirement for consent. In common law, an emergency exists when immediate treatment is required in order to save the life or preserve the health of the patient.[29] The rationale for this exception is that a reasonable person would consent to the treatment, and that a delay in treatment would lead to death or serious harm. In some provinces an emergency may be defined differently in statutory law than in common law, and so clinicians should be aware of the legislation in their own province. In Ontario statutory law, for example, an emergency exists if a person is apparently experiencing severe suffering or is at risk, if the treatment is not administered promptly, of sustaining serious bodily harm.[30]

The emergency exception to the requirement to obtain consent has important limitations. Clinicians should not administer emergency treatment without consent if they have reason to believe that the patient would refuse such treatment if he or she were capable. For example, in *Malette* v. *Shulman*[4] the physician gave a blood transfusion to a patient who, because of shock and severe facial injuries, was unconscious. The patient carried a signed card indicating that she was a Jehovah's Witness who did not want to receive blood transfusions under any circumstances. Despite this information, blood transfusions were given. Although the transfusions probably saved the patient's life, the court found the clinician liable for battery, holding that the written instructions were "clear, precise and unequivocal"[31] and that the clinician was bound by them unless he had good reason to believe that they did not truly represent the patient's wishes.[31]

A patient's incapacity does not exempt the physician from the requirement to obtain consent. If a patient is mentally incapable of making medical decisions, the clinician must obtain consent from a substitute. Assessing capacity and obtaining substitute consent will be discussed in detail later in this series.

The statutory law of some provinces permits nonconsensual treatment in specific circumstances, such as the involuntary admission of psychiatric patients and the treatment of irresponsible patients with communicable disease. Nonconsensual treatment will be discussed in a later article on voluntariness.

There are other potential exceptions to the requirement to obtain consent. "Therapeutic privilege" refers to the physician's withholding of certain information in the consent process in the belief that disclosure of this information would harm or cause suffering to the patient.[32] "Waiver" refers to a patient's voluntary request to forego one or more elements of disclosure. Therapeutic privilege and waiver will be discussed in the next article in this series.

**The cases**

Mr. A' s physician must decide whether to perform surgical repair of the aneurysm. Mr. A. is now an incapable person in a medical emergency, and no substitute decision-maker is available. In such a circumstance the surgeon may proceed without the patient's consent unless

a clear wish to the contrary has been expressed earlier. Should the surgeon proceed, given that Mr. A had previously refused elective repair of the aneurysm? Mr. A's refusal of elective surgery was based on his wish to continue caring for his wife. Therefore, Mr. A would likely want to undergo emergency surgery, because it would give him the best chance of continuing to care for his wife. Therefore, the surgeon may proceed without the patient's consent. If Mr. A had previously considered and refused emergency surgery, the surgeon would not be entitled to proceed.

Mr. B is obviously incapable of consenting to treatment of his pneumonia, and so the physician should obtain consent from Mr. B's wife. However, the clinician could administer emergency treatment such as oxygen and intravenous antibiotic therapy until Mr. B's wife arrives.

## Disclosure

**Abstract**
In the context of patient consent, "disclosure" refers to the provision of relevant information by the clinician and its comprehension by the patient. Both elements are necessary for valid consent. Disclosure should inform the patient adequately about the treatment and its expected effects, relevant alternative options and their benefits and risks, and the consequences of declining or delaying treatment. The clinician's goal is to disclose information that a reasonable person in the patient's position would need in order to make an informed decision. Therefore, clinicians may need to consider how the proposed treatment (and other options) might affect the patient's employment, finances, family life and other personal concerns. Clinicians may also need to be sensitive to cultural and religious beliefs that can affect disclosure.

Mr. C is 61 years old and works as a supervisor at a car assembly plant. He lives at home with his wife. He has been in good health, although he smokes a pack of cigarettes a day. At a routine checkup his physician notes a loud bruit at the left carotid artery. Mr. C, who is right handed, has never had a transient ischemic attack or stroke. A duplex Doppler ultrasound reveals significant stenosis of the left internal carotid artery; cerebral angiography reveals the degree of the stenosis to be 95%. Carotid endarterectomy is recommended; Mr. C discusses this proposal with the consultant vascular surgeon.

Mrs. D is 75 years old and lives at home with her husband. She has a remote history of gastric ulcers and has mild renal insufficiency as a consequence of hypertension. She visits her family physician because of acute worsening of chronic arthritis in her right shoulder. She is having trouble lifting and carrying objects. Her family physician is considering treating Mrs. D with a nonsteroidal anti-inflammatory drug (NSAID).

Mrs. E is 80 years old and lives alone in an apartment. She is fully independent and has never had a serious illness. She prefers not to see doctors. She is admitted to hospital after falling on the stairs and suffering a fracture of the femoral neck. A consultant in internal medicine diagnoses critical aortic stenosis; this is confirmed by echocardiography. The anesthetist visits

Mrs. E to discuss the proposed surgery and anesthesia. When he says that serious risks are associated with the surgery, Mrs. E says she does not want to know about them. She wants her hip fixed because she simply cannot live with reduced mobility. The anesthetist feels that he has a duty to disclose the risks of anesthesia.

Ms. F is 28 years old. She was admitted to hospital 6 weeks ago with an exacerbation of poorly controlled asthma. The hospital internist prescribed long-term oral corticosteroid therapy. Ms. F is now taking prednisone (20 mg/d) and has noticed weight gain and mood disturbance. She thinks that she should stop taking the medication. Her family physician has recently read about a case of avascular necrosis of the femoral head associated with prednisone therapy, but he believes that prednisone therapy is important to control Ms. F's asthma. He wonders whether the risk of avascular necrosis should not be disclosed, lest this information cause Ms. F to stop taking prednisone.

## What is disclosure?

"Disclosure," in the context of patient consent, refers to both the provision of relevant information by the clinician and its comprehension by the patient. Both elements are necessary for valid consent.

## Why is disclosure important?

### Ethics

In keeping with the ethical principles of patient autonomy and respect for persons, disclosure promotes patients' informed and reflective participation in health care decisions. Disclosure also promotes a continuing and trusting relationship between the patient and his or her physician.[1,2]

### Law

### Elements of disclosure

The necessary elements of disclosure as identified in Canadian statutory[3,4] and common[5] law are as follows: a description of the treatment and its expected effects (e.g., duration of hospital stay, expected time to recovery, restrictions on daily activities, scars); information about relevant alternative options and their expected benefits and relevant risks; and an explanation of the consequences of declining or delaying treatment. The patient must be given an opportunity to ask questions, and the clinician must respond to questions or requests for further information.

### Scope of disclosure

In Canada, the prevailing standard of disclosure is that of the "reasonable person."[3-5] This is an objective standard that requires the clinician to disclose information that a reasonable person in the patient's position would need in order to make an informed decision. The concept of "a reasonable person in the patient's position" may be understood by an example regarding disclosure of risks. Mr. C is considering carotid endarterectomy for asymptomatic stenosis of the carotid artery. Carotid endarterectomy has a known risk of immediate death or stroke.

These risks must be disclosed, because a risk of death, paralysis or permanent loss of a body function would be relevant (or "material") to a reasonable person. However, Mr. C is within 6 months of obtaining full pension benefits at work. A reasonable person in Mr. C's financial position would also need to know that the risk of having a stroke in the next 6 months would be higher with endarterectomy than with medical treatment.[6] In Canada, the reasonable-person standard for disclosure was established by the Supreme Court of Canada in the case of *Reibl* v. *Hughes*,[5] upon which the case of Mr. C is based.

### Waiver

"Waiver" refers to a patient's voluntary request to forego one or more elements of disclosure. For example, a patient may not wish to know about a serious prognosis (e.g., cancer) or about the risks of treatment. Because Canadian legislation and common law do not directly address the issue of waiver, clinicians should proceed cautiously when a patient appears to be requesting a waiver.

### Therapeutic privilege

"Therapeutic privilege" refers to the withholding of information by the clinician during the consent process in the belief that disclosure of this information would lead to the harm or suffering of the patient.[7]

The legal status of therapeutic privilege in Canada is uncertain. The case of *Meyer Estate* v. *Rogers*[8] involved a 37-year-old woman who died after intravenous injection of a contrast medium for a routine radiologic procedure. The radiologist claimed therapeutic privilege as a defense against the allegation that he failed to warn the patient of the risks of intravenous dye injection. The court rejected the defense on the grounds that therapeutic privilege was not applicable.[8] The judge concluded that "the Supreme Court of Canada has not . . . adopted or even approved the therapeutic privilege exception in Canada."[9]

The need for sensitivity to cultural norms may potentially support the exercise of therapeutic privilege. In some cultures therapeutic privilege is widely invoked, and it is unclear whether patients from these cultures should always be subjected to Western standards of consent.[10] However, given the legal status of therapeutic privilege in Canada, clinicians should avoid invoking therapeutic privilege. It is better for the clinician to offer information and allow the patient to refuse or accept further disclosure.

### Policy

Disclosure is an essential component of valid consent, and obtaining valid consent is a policy of the CMA[11] and other professional bodies.

### Empirical studies

The results of empirical studies of disclosure suggest that patients' desire for information closely agrees with the legal standard for disclosure. In one study more than 80% of a sample of surgical patients wanted to know about the nature of their illness, the reason for the surgery, the nature of the operation, the expected duration of their stay in hospital, the chances of a successful result, the expected time to return to normal daily activities and any special

precautions they would need to take after surgery.[12] Similar observations have been made with regard to patients' desire for information about anesthesia.[13-15]

Studies have indicated that 6% to 18% of patients prefer not to know about the risks of treatment.[12,13,16] However, this research evaluated patients who had already decided to proceed with surgery or had already undergone successful surgery and did not address the question of what they wanted to know about risks in order to consent to surgery.

Most studies in this area have found that routine verbal disclosure is not completely effective,[17-25] whereas written[26-30] or combined written and verbal disclosure[31-34] can improve patients' knowledge. Other aids to disclosure, such as bedside decision instruments[35] and interactive videodiscs,[36] are promising but require further evaluation.

**How should I approach disclosure in practice?**

Disclosure should be viewed as a process rather than as a discrete event. Several encounters between the clinician and patient may be needed before disclosure can be considered complete. For example, Ms. F and her clinician may need to discuss prednisone therapy on a number of occasions to ensure proper disclosure of benefits and risks. If a therapy is given over a prolonged period the disclosure process should continue. For example, if new information relevant to a patient's drug therapy becomes available it should be disclosed.

Effective communication is critical to the disclosure process. If the clinician fosters good communication the patient will be encouraged to provide personal information and express his or her values, goals and fears. A full discussion of effective physician-patient communication is beyond the scope of this article, but several relevant reviews are available.[37-41]

During the consent process clinicians should routinely address each element of disclosure, giving information about each of the areas described earlier (see "Elements of disclosure"). The goal is to disclose any information that a reasonable person in the patient's circumstances would want to know. Depending on the treatment in question, clinicians may need to consider how it, and other options, could affect the patient's employment, finances, family life and other personal concerns.

Disclosure should also take account of the patient's cultural and religious beliefs. For example, in some cultures a family-centered model of decision making is favored over one centered on the individual.[42] The clinician can encourage patients in such a situation to involve family members in the consent process. Although cultural sensitivity is a complex issue beyond the scope of this article, several reviews are helpful.[10,43,44]

Throughout each disclosure session the clinician should invite questions. Encouraging patients to restate information in their own words is one way to ensure that information has been understood. The clinician should document each discussion, noting the patient's questions and how these were answered. Special cultural or religious considerations are particularly important to document.

### The cases

The surgeon asks Mr. C if he has any worries or concerns about the proposed surgery and learns that Mr. C is due for full pension benefits in 6 months. The surgeon discloses that the risk of stroke within 6 months is higher with surgery than with medical treatment. Subsequently, the surgeon and Mr. C agree to continue acetylsalicylic acid therapy, to arrange for Mr. C's enrolment in a smoking cessation program and to re-evaluate the treatment decision in 6 months. The surgeon's note includes the reasons for the decision and a reminder of why Mr. C will return in 6 months.

Mrs. D has no questions about the "arthritis pill" because she trusts her physician, whom she has known for many years. The physician initiates a discussion of the risks -- in particular, gastrointestinal bleeding and renal insufficiency. Mrs. D appears concerned, and the clinician invites her to discuss this concern. Mrs. D explains that the shoulder pain must be relieved so that she can care for her young granddaughter, who will be visiting next month. The physician mentions that acetaminophen may also be effective and has a lower risk of side effects. Although pain relief is a high priority, Mrs. D would prefer to avoid side effects, particularly because she was once admitted to hospital because of her gastric ulcer. She agrees to try acetaminophen therapy for 2 weeks and, if there is no effect, to then try the NSAID. The physician makes a note of their discussion and arranges a follow-up appointment for 2 weeks hence.

Mrs. E has asked the anesthetist not to disclose further the risks associated with hip surgery. She says that her goal is to be able to walk and that further suffering from pain and immobility is not acceptable to her. She tells the anesthetist that any further discussion of risks will not change her mind but might upset her. The anesthetist respects Mrs. E's request but tells her that she can change her mind regarding the discussion of risks at any time. He also asks her if there are family members whom Mrs. E would like to involve in the decision-making process. Mrs. E wants her daughters to participate in the decision, and so the proposed surgery and its possible risks are disclosed to them. The entire discussion is documented, including Mrs. E's reasons for waiving further disclosure of the risks of surgery. Mrs. E undergoes uncomplicated repair of her hip fracture and returns home to live independently.

Ms. F should be informed of the risk of avascular necrosis of the femoral head. The clinician should not use therapeutic privilege to justify withholding this information.

## Capacity

### Abstract

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. A person may be "capable" with respect to one decision but not with respect to another. Clinicians can usually identify patients who are clearly capable or incapable, but in some cases a clinical capacity assessment is required. Such assessment may consist of cognitive status testing, general impressions of capacity or specific

capacity assessment. Specific capacity assessment, in which the clinician evaluates the patient's ability to understand pertinent information and appreciate its implications, is probably the optimal method. When conducting a specific capacity assessment, the clinician must ensure that the disclosure of information is effective and must evaluate the patient's reason for his or her decision. If the assessment suggests that the patient is incapable, further assessment is generally recommended.

Mr. G is 42 years old and is receiving neuroleptic therapy for chronic schizophrenia. Although he is unemployed he functions independently in the community. Because he believes that his neighbors break into his house and steal his money when he is out, he rarely leaves his apartment. He calls his family physician because of a sore throat. The physician makes a house call and obtains a throat swab, which reveals a *Streptococcus pyogenes* infection. The physician recommends antibiotic therapy.

Mr. H is a 65-year-old man admitted to hospital because of acute imbalance and clumsiness in the left arm. He is diagnosed with atrial fibrillation and infarction of the left cerebellar hemisphere. His clinician recommends warfarin therapy, but Mr. H. repeatedly refuses.

Mrs. I is a 79-year-old woman with noninsulin-dependent diabetes mellitus who is admitted to hospital with gangrene of the first and second toes of her right foot. She lives alone and does not like doctors. She receives intravenous antibiotic therapy for 1 week without response. Her clinicians recommend amputation of the affected toes, but she says "I don't know what you will do with them after you cut them off."

Mr. J is 74 years old and has severe Parkinson disease. He is admitted to hospital with psychosis caused by bromocriptine therapy. His clinician wishes to start treatment with clozapine, an antipsychotic drug with minimal extrapyramidal side effects but potentially severe hematologic side effects. When the clinician attempts to obtain consent Mr. J is unable to respond to any questions.

## What is capacity?

"Capacity," or "decision-making capacity," is the ability to understand information relevant to a decision and to appreciate the reasonably foreseeable consequences of a decision or lack of decision. Capacity is specific to particular decisions: a person may be capable with respect to deciding about a place of residence, for example, but incapable with respect to deciding about a treatment. Capacity can change over time. For example, a person may be temporarily incapable because of delirium but subsequently recover his or her capacity.

## Why is capacity important?

### Ethics

The ethical principles of patient autonomy and respect for persons require that capable people be allowed to make their own informed decisions. However, the ethical principle of physician beneficence requires that incapable people be protected from making decisions that are harmful or that they would not make if they were capable.

## Law

In law, capable patients are entitled to make their own informed decisions. If a patient is incapable, the physician must obtain consent from a designated substitute decision-maker. In common law and under some legislation patients are *presumed* capable. If it is unreasonable to presume capacity, then a capacity assessment should be undertaken.

In Canadian common law there is no age below which a person is not presumed capable. A minor can give consent if he or she is able to understand the information about a treatment and to appreciate the risks and likely consequences of the treatment.[1] Some provinces have legislation that establishes the age of consent to treatment (Table 1); clinicians should familiarize themselves with the legislative requirements in their own province.

**Table 1. Age of consent for medical treatment in Canada**

| | |
|---|---|
| Prince Edward Island | A person must be at least 18 years of age or married to consent to surgery in a public hospital.[2] |
| New Brunswick | The age of consent for medical treatment is 16 years of age. A younger person may consent if, in the opinion of the attending physician or dentist and one other physician or dentist, he or she is capable of understanding the nature and consequences of treatment, and the treatment is in the person's best interests with respect to continued health and well being.[3] |
| Quebec | The age of consent is 14 years of age if the treatment is required because of the patient's state of health. For a child under 14 years of age parental consent must be obtained unless a judge orders otherwise or the child's life is in danger.[4] |
| Saskatchewan | A person must be at least 18 years of age or married to consent to surgery in a public hospital.[5] |
| British Columbia | A person who has reached the age of 16 years can consent to treatment if the health care provider has made a reasonable attempt to obtain consent from the person with parental authority and a written opinion is obtained from a second physician or dentist that the treatment is in the person's best interests with respect to continued health and well being.[6] |
| Other provinces | The remaining provinces have no legislation that establishes an age of consent to treatment. In common law there is no age of consent. A minor can consent if he or she is capable of understanding the information about a treatment and of appreciating the risks and likely consequences of the treatment.[1] |

## Policy

Capacity is an essential component of valid consent, and obtaining valid consent is a policy of the CMA[7] and other professional bodies.

**How should I approach capacity in practice?**
A clinician develops a general impression of a patient's capacity during the clinical encounter. In most cases the clinician has little reason to question the patient's capacity and focuses on other aspects of the consent process. However, some patients, such as those who are comatose or who have severe dementia, are obviously incapable. In such cases the clinical assessment of capacity is straightforward, and substitute consent is required. (Substitute decision-making is discussed in a later article in this series.)

In some situations clinicians may be unsure about a patient's capacity. The patient may have a neurologic or psychiatric disease or may be behaving in a way that indicates lack of understanding. Although refusal of recommended treatment may cause a clinician to *question* a person's capacity,[8] refusal of treatment should not be considered evidence of incapacity.9 Most refusals are caused by factors other than incapacity.[10]

When a clinician is unsure about a patient's capacity an assessment is needed. The initial objective of assessment is to screen for incapacity. Patients who appear to be incapable after the screening assessment generally require further evaluation. Clinicians may use three different measures of capacity: cognitive function testing, general impressions of capacity and specific capacity assessments.

Cognitive function tests such as the Mini Mental State Examination[11] are reliable, easy to administer and familiar to clinicians in a wide variety of settings. However, although cognition and capacity are related, they are not identical.[12–15] Most measures of cognitive status do not evaluate several cognitive functions, such as judgment and reasoning, that are relevant to capacity.[16] A person may have a perfect cognitive test score but still be incapable by virtue of delusions that directly affect the treatment decision. Another limitation of cognitive status tests is that cut-off scores for identifying incapacity have not been established.

Gaining a general impression of a patient's capacity is a simple and quick method of assessment but can be unreliable,[17] inaccurate[13,14] and easily biased.[18]

In a specific capacity assessment the clinician discloses information relevant to the treatment decision and then evaluates the person's ability to understand this information and to appreciate the consequences of his or her decision. The Aid to Capacity Evaluation is a decisional aid to assist clinicians in carrying out specific capacity assessments.[19] It prompts clinicians to probe seven relevant areas (Table 2), provides sample questions for the evaluation of each area and gives suggestions for scoring. Other decisional aids have been developed to assist with the assessment of the patient's capacity to complete an advance directive[20] and to consent to treatment,[21–26] and to assist with the simultaneous assessment of several types of capacity.[27]

**Table 2: Relevant areas of patient capacity specified in the Aid to Capacity Assessment[19]**

| |
|---|
| • Ability to understand the medical problem.<br>• Ability to understand the proposed treatment.<br>• Ability to understand the alternatives (if any) to the proposed treatment.<br>• Ability to understand the option of refusing treatment or of it being withheld or withdrawn.<br>• Ability to appreciate the reasonably foreseeable consequences of accepting the proposed treatment.<br>• Ability to appreciate the reasonably foreseeable consequences of refusing the proposed treatment.<br>• Ability to make a decision that is not substantially based on delusions or depression. |

Specific capacity assessments have several strengths. First, they directly assess the patient's actual functioning while he or she is making a decision, which is exactly what the legal definition of capacity requires. Second, they are clinically feasible and quick: the median time for Aid to Capacity Evaluation assessments is 12 minutes.[19] Finally, specific capacity assessments are flexible and can easily be adapted to various clinical circumstances.

However, specific capacity assessments have certain drawbacks. First, they are only as good as the accompanying disclosure. If the clinician does not disclose information effectively, the capacity assessment will be inaccurate. Therefore, excellent communication skills are critical to accurate assessment. In practice, the process of disclosure should continue throughout the capacity assessment. For example, if a patient does not initially appreciate that he or she may be able to walk after a below-knee amputation, then this information should be redisclosed. Then the clinician can re-evaluate whether this consequence of below-knee amputation has been understood.

A second problem with specific capacity assessments relates to the evaluation of a patient's reasons for a decision. The goal is to ensure that the decision is not substantially based on a delusion and is not the result of depression. However, some "delusions" may represent personal, religious or cultural values that are not appreciated by the clinician. Similarly, it is difficult to determine whether a decision is substantially affected by the cognitive features of depression, such as hopelessness and feelings of worthlessness, guilt and persecution.[28,29]

A third problem is that a patient's capacity may fluctuate. If a person appears to be incapable the clinician should determine whether any reversible factors such as delirium or a drug reaction are at work. If such factors are identified the clinician should attempt to eliminate or minimize them and then repeat the assessment. There may also be factors that prevent a person from communicating effectively with the clinician, such as a language barrier or speech disturbance. Such factors must be addressed to ensure accurate capacity assessment.

Finally, clinicians may find it difficult to perform unbiased capacity assessments, particularly when the patient's choice goes against their recommendations. It is important to remember that agreement or disagreement with the patient's decision is not at issue; the purpose of capacity assessment is to evaluate the person's ability to understand relevant information and to appreciate the consequences of a decision.

If the result of screening indicates that a patient may be incapable, further expert assessment is generally recommended, particularly if the clinician is unsure about the assessment or if the person challenges the finding of incapacity. Expert assessments can be conducted by individual practitioners (e.g., psychiatrists and psychologists), hospital ethics committees or legal review boards. If a finding of incapacity is based primarily on the clinician's interpretation of the person's reason for his or her decision, then the clinician should seek further input from others, such as the patient's family or relevant representatives from the patient's cultural or religious group. If the clinician suspects that a decision is based substantially on delusions or depression, then psychiatric evaluation is recommended.

**The cases**

Mr. G's clinician notes that the patient has no known allergies and has taken penicillin in the past. The clinician explains that the pills are to treat the sore throat but may cause diarrhea or a rash. The clinician asks Mr. G to review the information to ensure that everything is clear. Mr. G says: "You're giving me these pills to help my throat. If I get diarrhea or any skin problems I should stop and let you know." The clinician concludes that Mr. G is able to understand the relevant information and to appreciate the reasonably foreseeable consequences of accepting treatment. Furthermore, the decision to accept is not based on a delusion, but on a desire for symptom relief. The entire capacity assessment takes less than 1 minute.

Mr. H's specific capacity assessment shows that he has the ability to understand his condition ("I have had a stroke to the left cerebellum, which has left me clumsy on the left side. It was caused by a blood clot from the heart"), the proposed treatment ("You want to thin my blood with warfarin"), the option of refusing ("I don't want it"), as well as the ability to appreciate the reasonably foreseeable consequences of refusing the treatment ("I might have another stroke without the pills, but I don't want them") and of accepting it ("You say that the pills might reduce the chance of stroke, but it can also cause bleeding"). Explaining the reason for his refusal, Mr. H says: "I think that the women who draw the blood are vampires. You want to thin my blood so it is easier for them to drink." Mr. H is subsequently evaluated by a psychiatrist, who diagnoses acute mania. Mr. H's wife later reveals that Mr. H had previously been diagnosed with manic depressive disorder but had stopped his lithium therapy several months before his stroke.

Mrs. I's specific capacity assessment showed that she had the ability to understand her condition ("My toes are dead. They are very smelly"), the proposed treatment ("You want to cut off my toes"), and the option of refusing ("I do not want you to cut them off"), as well as some ability to appreciate the reasonably foreseeable consequences of refusing ("You say I will die, but I don't know about this. I wonder what you will do with my toes after you cut them off. I don't really trust the doctors. I think they just want to give the students some practice"). Mrs. I reveals that she is a concentration-camp survivor with a deep mistrust of physicians. She also

says that 7 years ago when she had gangrene of the left foot and refused amputation the foot had healed. Because the clinician remains unsure of Mrs. I's capacity and suspects depression, a psychiatric consultation is requested. Mrs. I admits to having a persistent depressed mood and several vegetative signs of depression. However, she denies feelings of hopelessness, guilt, persecution or worthlessness. Ultimately, Mrs. I is felt to be capable but depressed. She accepts treatment for depression. Her foot condition stabilizes and at 1 year of follow-up she is able to walk but still requires daily treatments for her foot.

Mr. J is re-evaluated 4 hours later, at which time he has gained maximum benefit from the medication for his Parkinson disease. At this time, he is able to communicate and answer questions, and is clearly capable.

## Voluntariness

**Abstract**
In the context of consent, "voluntariness" refers to a patient's right to make health care choices free of any undue influence. However, a patient's freedom to make choices can be compromised by internal factors such as pain and by external factors such as force, coercion and manipulation. In exceptional circumstances -- for example, involuntary admission to hospital -- patients may be denied their freedom of choice; in such circumstances the least restrictive means possible of managing the patient should always be preferred. Clinicians can minimize the impact of controlling factors on patients' decisions by promoting awareness of available choices, inviting questions and ensuring that decisions are based on an adequate, unbiased disclosure of the relevant information.

Mrs. K, who is 85 years old, was born in Germany but is fluent in English. She lives alone and carries out most activities of daily living independently. One day she collapses on her way to the grocery store. She is taken to hospital, where a large subarachnoid hemorrhage is diagnosed. She is comatose for 3 days. When she awakes on the third night she appears extremely confused and speaks only in German. She repeatedly climbs out of bed and pulls at her bladder catheter. The surgeon wonders if she should be physically restrained.

Mr. L is 65 years old and has been admitted to hospital with severe iron-deficiency anemia. After his condition is stabilized by means of a blood transfusion, an endoscopy is ordered. The attending physician tells Mr. L that he will "have a test" because "he must be bleeding from the bowel." He adds, "I want you to have this test before you go home." Mr. L, dressed in a hospital gown, is lying on a stretcher in the hallway outside the endoscopy suite when the endoscopist arrives.

Mr. M is 90 years old and lives with his wife in a senior's apartment. He is independent in most activities of daily living. He is admitted to hospital with acute myocardial infarction complicated by mild congestive heart failure. The emergency physician discusses advanced cardiac life support (cardiopulmonary resuscitation [CPR], and electrical cardioversion and defibrillation). During the discussion, the clinician emphasizes that CPR causes broken ribs

and, even when successful, leaves the patient with severe neurologic impairment. Mr. M declines CPR and is consequently admitted to a ward bed without continuous cardiac monitoring.

**What is voluntariness?**

In the context of consent, "voluntariness" refers to a patient's right to make treatment decisions free of any undue influence. A patient's freedom to decide can be impinged upon by internal factors arising from the patient or the patient's condition or by external factors. External factors, which are the focus of this article, include the ability of others to exert control over a patient by force, coercion or manipulation.[1] Force involves the use of physical restraint or sedation to enable a treatment to be given. Coercion involves the use of explicit or implicit threats to ensure that a treatment is accepted (e.g., "If you don't let us do these tests, then we will discharge you from the hospital!"). Manipulation involves the deliberate distortion or omission of information in an attempt to induce the patient to accept a treatment.[2,3] Mr. M is a manipulated patient: no reasonable person would consent to CPR if he or she believed that it always resulted in pain and severe brain damage, with no hope of any benefit.

The requirement for voluntariness does not imply that clinicians should refrain from persuading patients to accept advice. Persuasion involves appealing to the patient's reason in an attempt to convince him or her of the merits of a recommendation.4 In attempting to persuade the patient to follow a particular course of action, the clinician still leaves the patient free to accept or reject this advice.

**Why is voluntariness important?**

**Ethics**

Voluntariness is an ethical requirement of valid consent. It is grounded in several related concepts, including freedom, autonomy and independence.[5] The goal of the consent process is to maximize the opportunity for decisions to be reached autonomously.[6] Practically, it requires the physician to ensure that situations do not arise in which the patient's actions are substantially controlled by others. There is an inherent power imbalance in the physician–patient relationship; clinicians should strive to minimize this imbalance by fostering autonomous decision-making by their patients.

**Law**

Voluntariness is a legal requirement of valid consent. In *Beausoleil* v. *Sisters of Charity*[8] a young woman about to undergo spinal surgery repeatedly requested a general anesthetic and refused a spinal anesthetic. After the patient had been sedated, the anesthetist convinced her to have a spinal anesthetic. The patient was subsequently paralyzed as a result of the procedure and successfully sued the anesthetist. In testimony, a witness said that the patient "refused [the spinal anesthetic], but they continued to offer it to her; finally she became tired and said: 'You do as you wish' or something like that."[9] The judge stated that the patient's agreement to the spinal anesthetic was involuntary, because it rested on "words which denote defeat, exhaustion, and abandonment of the will power."[9]

In *Ferguson* v. *Hamilton Civic Hospitals et al*,[10] a patient unsuccessfully sued for battery after undergoing an angiogram that resulted in quadriplegia. Although the suit was unsuccessful, the court was critical of the circumstances in which the consent was obtained and suggested that "the informing of a patient should occur at an earlier time than when he is on the table immediately before undergoing the procedure."[11] It has been suggested that obtaining consent just before a major procedure is problematic, because "the setting and the immediacy of the medical procedure militate against a patient being able to make a free or voluntary decision."[12]

Some legislation allows for treatment to be given in certain circumstances without the patient's volition. For example, irresponsible people with communicable diseases may be treated against their objection, as in the case of patients with tuberculosis who are noncompliant with treatment. Also, all provinces allow for the involuntary admission of patients to psychiatric facilities, provided they present an immediate risk to themselves or others, or are unable to take care of themselves. However, in most provinces, a patient who is admitted involuntarily may not be treated without consent except in emergency situations in which the patient is incapable. Because of the coercive nature of such circumstances, extra care should be taken in obtaining consent from patients who have been admitted involuntarily.

## Policy

Voluntariness is an essential component of valid consent, and obtaining valid consent is a policy of the CMA[14] and other professional bodies.

### Empirical studies

Psychiatric inpatients may be subject to explicit or implicit coercion even when their admission has been voluntary.[15–17] However, even patients who require involuntary admission can be given some measure of control over their situation by being allowed to choose the method of restraint.[18]

Institutionalization in nonpsychiatric hospitals or long-term care facilities can also be coercive. Even simple instructions to patients (e.g., "Don't get out of bed until after your breakfast") can give the patient a sense of diminished control.[19] Interventions that enhance the ability of long-term residents to exert control result in a greater sense of well-being,[20] and many long-term care facilities have developed successful programs to reduce the use of restraints.[21]

Outpatients are less likely than inpatients to be subjected to force and coercion,[22] but they may be susceptible to manipulation. Although we are unaware of any data on the incidence of manipulation, many studies indicate that decisions can easily by influenced by the manner in which information is presented.[23–26] It is possible for such manipulation to occur in clinical practice.

### How should I approach voluntariness in practice?

Internal and external controlling factors can affect patients' decisions about treatment (Fig.1). For example, a patient with metastatic prostate cancer and bone pain is subject to internal controlling factors. A symptom-free life without treatment is not possible, and the patient must make some decisions while suffering severe pain, at least until the pain is treated. These

internal factors arise from the patient's medical condition rather than from an external source, such as any action by the clinician. The clinician's role is to minimize the potential controlling effect of these internal factors. For example, the clinician can reduce the impact of acute pain on decision-making by deferring nonurgent decisions until the pain has been treated.

External controlling factors may be related to the clinician, the health care setting or to other people such as family and friends. We will focus here on the clinician and the health care setting; the problems that can arise when family, friends or others exert excessive control are beyond the scope of this article.

In the few circumstances in which it is acceptable for clinicians to use force, the least restrictive technique possible should be preferred. For example, if a patient is at immediate risk of harming himself or herself, simple observation in a supervised environment, rather than physical restraint or sedation, may be sufficient. Similarly, an elderly patient with delirium who is falling out of bed can be moved to a mattress on the floor so that the risk of falling is eliminated without physical restraint.

In psychiatric and long-term care institutions a patient advocate can help the clinician ensure that consent is not coerced.[27] Clinicians can also take steps to minimize the coercive nature of institutions by enhancing the patient's sense of choice. Useful strategies might include encouraging patients to involve their family in decisions, encouraging them to ask questions and promoting their awareness of the choices available to them (e.g., "I would like you to have a test tomorrow. Do you want to talk about it with your family? Is there any reason to delay?").

Clinicians can also take steps to minimize the potential for manipulation. First, because patients can be manipulated when the information they receive is incomplete, clinicians should ensure that adequate information has been disclosed to the patient. Second, manipulation can occur when information is presented in a biased fashion. A useful strategy is to ask patients to review information in their own words. Also, if a patient who accepts therapy because of its potential benefits continues to accept it when its potential risks are emphasized, then the clinician can be more confident that this decision has not been manipulated.[29]

**The cases**

The surgeon tries to determine why Mrs. K is climbing out of bed. A German-speaking relative is contacted; she ascertains that Mrs. K is disoriented but is also very worried about her cat at home, who needs to be fed. The relative reassures Mrs. K that a neighbor has been feeding the cat. Mrs. K is visibly relieved and becomes less agitated. The surgeon decides that Mrs. K can be monitored safely without the bladder catheter, and the catheter is removed. The relative agrees to stay overnight to ensure that Mrs. K does not fall out of bed. Mrs. K is not restrained.

The endoscopist asks Mr. L to review the reasons for the test in his own words. Mr. L says that he's got "no choice but to have the test" because "my doctor needs it done before I go home." Because the endoscopy is not an emergency, the endoscopist calls the attending physician, who agrees that the test should be delayed. After a further discussion that afternoon, Mr. L consents to the endoscopy, which is performed the next morning.

On the medical ward, Mr. M's attending physician asks why he has refused advanced cardiac life support. Mr. M explains that if his heart stopped then he would "rather be dead than a vegetable with broken ribs." He adds that he hopes to be alive and able to attend his granddaughter's wedding next month. The clinician discusses the potential benefit of defibrillation in the event of a witnessed cardiac arrest related to acute myocardial infarction. Despite the potential benefits of CPR, Mr. M says he would prefer to forego the treatment, because "I've lived a good life and I'm ready to go." He remains on the medical ward, recovers and attends his granddaughter's wedding.

## Substitute decision-making

**Abstract**
Substitute decision-making is a means of making health care decisions on behalf of people who are incapable of making these decisions for themselves. It is based on the ethical principle of respect for autonomy. Substitute decision-making poses two main questions: Who should make the decision for the incapable person, and, How should the decision be made? Because the applicable statutory and common law varies across Canada, clinicians should become familiar with the legal requirements of their own province or territory.

Mr. N is a 35-year-old man with advanced AIDS who has recently been diagnosed with AIDS-related dementia. When he was still capable he told his partner and close family members that if he ever "lost his mind" because of his HIV infection he would want to receive only comfort measures for any new medical problem. During the past 2 weeks Mr. N's caregivers have noticed that he is having increasing difficulty breathing. In view of his medical history they think he probably has a recurrence of *Pneumocystis carinii* pneumonia (PCP). A chest x-ray shows probable PCP. The physician knows that Mr. N has had a lot of difficulty with adverse drug reactions in the past and wonders whether or not the patient should be admitted to hospital for further investigations and treatment.

Mr. O is an 85-year-old widower who was diagnosed with Alzheimer disease 10 years ago. His clinical condition has deteriorated, and he is no longer able to maintain an adequate energy intake by mouth. Feeding by nasogastric tube has been tried, but the patient repeatedly pulls out the tube. The option of using a surgically placed feeding tube is being considered by his caregivers. His family include five adult children, all of whom are available. Two of them think their father would want the feeding tube, two others think he would not want it, and one does not know what he would want.

Mrs. P, a 73-year-old widow with advanced chronic obstructive pulmonary disease and osteoporosis, has recently moved into a nursing home because of deteriorating health. Her closest family members include three married children. One daughter lives in the same city, and the other two children live more than an hour away by car. Mrs. P's breathing deteriorates suddenly and she is transferred to hospital for assessment and treatment. When she is seen in the emergency department she is confused because of either respiratory failure or the toxic effects of an infection. Blood analysis reveals significant hypoxemia and respiratory acidosis.

The attending physician wonders whether or not Mrs. P should be intubated. She has never required intubation before, and her hospital records give no instructions with regard to resuscitation. Mrs. P's daughter has just arrived and is waiting to talk to the physician.

**What is substitute decision-making?**

In theory, incapable patients have the same right to consent to diagnostic tests and treatments as do capable patients. In practice, however, incapable patients cannot exercise this right. Substitute decision-making is a means of making decisions about health care on behalf of patients who are incapable.

**Why is substitute decision-making important?**

**Ethics**

The primary ethical rationale for substitute decision-making is the principle of respect for autonomy.[1] It is an attempt, albeit an imperfect one, to extend the patient's control over his or her own health care. This rationale has a number of important practical implications.

First, the substitute decision-maker should be the person or persons with the best knowledge of the patient's specific wishes, or of the patient's values and beliefs, as they pertain to the present situation. In general, close relatives are preferred as substitute decision-makers in the belief that they will know the patient well enough to replicate the decision that the patient would make if he or she were capable. Of course, the patient may be estranged from his or her spouse, parents, children or siblings, and in some instances a friend or perhaps the patient's primary care physician or nurse will know the patient's wishes best.

Second, the task of substitute decision-makers is to decide not how they would want to be treated were they in the patient's situation but, rather, how the patient would want to be treated. Despite the best intentions and most sincere efforts of those involved, it sometimes remains a mystery what the patient would have chosen. When good information about the patient's wishes, or values and beliefs, is lacking, or when the available information is contradictory, the decision-maker may be forced to make a judgment as to the patient's best interests in the given circumstances.

Finally, when relatives disagree they should be encouraged to focus their attention on the question of what the patient would want to be done or what is in the patient's best interests.

**Law**

Nonstatutory law relating to substitute decision-making is rather uncertain. It is probably the case that family members do not have the legal power to make health care decisions on behalf of an incompetent adult patient and that only a court-appointed guardian, or the court itself, has that power.[2,3] In practice, of course, family members are often consulted and viewed as having decision-making authority. The Yukon Territory, British Columbia, Ontario, Quebec and Nova Scotia have recognized that this situation is unsatisfactory and have enacted legislation giving family members the right to make health care decisions on behalf of incompetent patients. British Columbia, Manitoba, Ontario, Quebec, Nova Scotia and Newfoundland have passed legislation that enables individuals to designate the person they

wish to make health care decisions for them once they are no longer able to make such decisions themselves. Because the applicable statutory and common law varies across Canada, it is advisable that practitioners become familiar with the legal requirements in their own province or territory.

### Policy

Substitute decision-making is an important part of the health care policies of health care facilities and professional organizations.[4,5] For instance, the CMA policy on resuscitative interventions includes provisions related to substitute decision-making.[6]

### Empirical studies

Studies have demonstrated that partners and close family members cannot accurately predict patients' preferences for life-sustaining treatments.[7–9] This should raise concern about uninformed substitute decision-making and encourage advance care planning. (Approaches to advance care planning will be discussed in the next article in this series.)

## How should I approach substitute decision-making in practice?

The process of substitute decision-making poses two important questions. First, who should make the decision for the incapable person? Second, how should the decision be made? Although the answer to these questions varies from one jurisdiction to another, the overall goal of substitute decision-making is to replicate the decision the patient would make if he or she were still capable.

The most appropriate person to act as substitute decision-maker is someone appointed by the patient while he or she is still capable, or by a proxy advance directive or by a court. Other substitute decision-makers, in their usual order of ranking, include the patient's spouse or partner, child, parent, sibling or other relative. In some jurisdictions a public official will serve as substitute decision-maker for a patient who has no such person available.

The criteria on which the decision should be based are the specific wishes previously expressed by the patient, the patient's known values and beliefs, and the patient's best interests. The patient's wishes are those preferences expressed by the patient while he or she was competent that seem to apply to the decision that needs to be made. Some patients record their wishes in an advance directive. Values and beliefs are less specific than wishes but allow the substitute decision-maker to infer, in light of other choices the patient has made and his or her approach to life in general, what he or she would decide in the present situation. The calculation of a patient's best interests is based on objective estimates of the benefits and burdens of treatment to the patient.

The role of the health care professional is to facilitate the process of substitute decision-making by providing information that will enable the substitute to make an informed choice on the patient's behalf. Health care professionals should guide the substitute to consider the patient's previously expressed wishes, values and beliefs, or best interests (in this order). When it is apparent that the substitute is making a choice that is significantly different from what the patient might have chosen, health care providers find themselves in a difficult situation and should seek advice from colleagues, ethics committees and legal counsel.

### The cases

Mr. N is incapable because of his AIDS-related dementia. The situation is not an emergency. The physician speaks to Mr. N's partner and close family members, who all agree that he would not want to be admitted to hospital to undergo any invasive procedures. They feel he would want to go home, perhaps with supplemental oxygen therapy to relieve some of his distress. They tell the physician that after his last episode of PCP Mr. N instructed them that he would never wish to go through the necessary treatment again. Palliative home oxygen therapy is arranged, and the patient dies 72 hours later.

Mr. O is permanently incapable because of his Alzheimer disease. The problem is that his five children cannot agree on what treatment he would choose. In such situations, sensitive counseling with the family is needed; if this still does not resolve the conflict, referral to a board (e.g., the Consent and Capacity Board in Ontario) or to the courts might be required. As soon as the conflict with respect to who will make the decision for the patient is resolved, the proposed treatment can be discussed with that person. In this case, a social worker is able to bring the family together to reach a consensus as to which children are in the best position to act as substitute decision-makers. The patient dies from progressive Alzheimer disease 6 months later without a feeding tube being placed.

Mrs. P is judged to be temporarily incapable. After discussing the patient's incapacity, the physician asks the daughter whether she knows what her mother would want if the situation deteriorates further. The daughter says that Mrs. P's quality of life declined after her husband died. Although she has never discussed this sort of situation directly with her mother, she does not think that her mother would want resuscitation. However, she is uncomfortable making this decision on her own. The physician suggests that she consult with her siblings. The physician says that in the meantime everything possible will be done to avoid intubation; however, intubation will proceed if it becomes medically necessary. Two hours later the daughter reports to the physician that all of the children feel that Mrs. P would refuse intubation if she were capable. Although the physician makes it clear that Mrs. P might be able to make this decision herself if she recovers from the current episode, the daughter requests that a "do not intubate" order be placed on the patient's chart. The physician agrees to write the order and plans to discuss it with the patient if her capacity improves.

## Advance care planning


### Abstract

Advance care planning is a process whereby a patient, in consultation with health care providers, family members and important others, makes decisions about his or her future health care. Grounded in the ethical principle of autonomy and the legal doctrine of consent, advance care planning helps to ensure that the norm of consent is respected should the patient become incapable of participating in treatment decisions. Physicians can play an important role by informing patients about advance care planning directing them to appropriate resources, counseling them as they engage in advance care planning and helping them to tailor advance directives to their prognosis.

Mrs. Q is 63 years old and has no significant history of illness. She presents for a routine visit to her family physician. She recently read a newspaper article about a new law on living wills and wants to obtain some advice about them.

Mr. R is a 40-year-old man who was diagnosed 2 years ago with HIV infection. He presents to an internist with symptoms of early dementia. The internist considers what Mr. R. should be told about advance directives.

What is advance care planning?

Advance care planning is a process whereby a patient, in consultation with health care providers, family members and important others, makes decisions about his or her future health care.[1] This planning may involve the preparation of a written advance directive.[2,3] Completed by the patient when he or she is capable, the advance directive is invoked in the event that the patient becomes incapable. (The question of capacity is discussed in the third article in this series [see sidebar].) Advance directives indicate whom the patient would want to make treatment decisions on his or her behalf and what interventions the patient would or would not want in various situations.

**Why is advance care planning important?**

**Ethics**

Advance care planning helps to ensure that the norm of consent is respected when sick people are no longer able to discuss their treatment options with physicians and thereby exercise control over the course of their care. This norm is grounded in the principle of self-determination and respect for autonomy, a classic expression of which is Justice Benjamin Cardozo's statement in 1914 that "Every human being of adult years and sound mind has the right to determine what shall be done with his own body."[4]

Although the principle of self-determination places high value on individual liberty, the usefulness of advance care planning is not limited to those whose world-view valorizes individualism. Advance care planning also rests on the principle of respect for persons, and this respect must extend to those whose cultural values emphasize the interdependence of human beings and the well-being of the family or community as a whole. Advance care planning recognizes that sick people suffer a loss of dignity when they cannot command respect for their considered and cherished intentions and that such intentions may be shaped by cultural values.

Advance care planning cannot avert all ethical uncertainties and conflicts in clinical decision-making. Some patients change their views as time passes, and others request life-prolonging interventions that subsequently prove to be unrealistic. Moreover, substitute decision-makers are not always sure that a patient's situation is equivalent to that described in an advance directive.

## Law

British Columbia,[5] Alberta,[6] Manitoba,[7] Ontario,[8,9] Quebec,[10] Nova Scotia,[11] Prince Edward Island[12] and Newfoundland[13] have legislation supporting the use of advance directives. (In British Columbia, Alberta and Prince Edward Island, this law has not yet been proclaimed.) An advance directive is referred to in law by various names: "representation agreement" (British Columbia), "personal directive" (Alberta), "health care directive" (Manitoba), "power of attorney for personal care" (Ontario), "mandate given in anticipation of . . . incapacity" (Quebec), "consent agreement" (Nova Scotia) and "advance health care directive" (Newfoundland). The legislation varies from province to province with respect to the scope of advance directives, who can act as proxy for the patient, requirements for witnessing the advance directive, procedures for activating the advance directive, and so on. Physicians should familiarize themselves with the legislation in their province or territory. Even when there is no legislation, legal decisions such as that made in *Malette* v. *Shulman* and other cases[14,15] suggest that advance directives may still be legally valid.

## Policy

The CMA supports the use of advance directives,[16] and some hospitals and long-term care facilities have policies regarding advance directives.[17,18]

## Empirical studies

Key findings from empirical studies can be summarized as follows.

- Advance directives are generally viewed in a positive light by physicians and patients.[19–29] For example, 85% of family physicians in Ontario favored the use of advance directives,[30] and 62% of medical outpatients wanted to discuss their preferences with regard to life-sustaining treatment.[31]
- Only 12% of Ontarians and 10% of Canadians have completed an advance directive form.[32,33]
- People change their preferences over time with respect to life-sustaining treatment.[34,35]
- Cultural values play an important role in advance care planning.[36,37]
- The implementation of programs to encourage advance care planning is associated with increased use of advance directives.[38–47]
- Few studies have been done on substitute decision-making for incapable persons with or without advance care plans and advance directives.[48,49]
- The effect of advance directives on health care costs has been the subject of debate.[50–54] Findings from the largest and most recent randomized trial do not support the hypothesis that the use of advance directives decreases health care utilization or costs.[55]

**How should I approach advance care planning in practice?**
The previous article in this series addressed the role of advance directives in substitute decision-making for incapable patients [see sidebar]. In this article we focus on the process of planning care with capable patients.

The main goal of advance care planning is "to ensure that clinical care is shaped by the patient's preferences when the patient is unable to participate in decision making."56 Moreover, it has recently been recognized that such planning is a social process that requires communication among all concerned; it is not simply the act of completing an advance directive form.[1,57]

The role of the physician in advance care planning is still being defined. Some authors believe that the physician's role is central. For example, Emanuel and associates[57] describe a framework for advance care planning within the context of the physician–patient relationship. This conception does not take into account the fact that many Canadians complete advance directives with the assistance of a lawyer in the context of estate counseling, or that over 2 million people requested Power of Attorney for Personal Care forms from the Office of the Public Guardian and Trustee after the Substitute Decisions Act was passed in Ontario. A broader view of advance care planning suggests that it occurs outside the context of the physician–patient relationship. Some preliminary research findings support this view.[58]

Understanding advance care planning in a broader social context calls for a re-evaluation of the part that physicians and other health care providers have to play. If advance care planning occurs within families, for example, the physician should support that planning rather than direct it. The physician's primary role is that of educator. Physicians who raise the issue of advance care planning with patients who are unaware of their rights with respect to advance directives perform a valuable service. Patients who request assistance with advance care planning should first be directed to relevant information sources; these include documents provided by provincial governments, self-help publications such as *Let Me Decide*[59] and the *Living Will* booklet and video available through the University of Toronto Joint Centre for Bioethics.

Once a patient has obtained general information about advance care planning, the physician can help him or her to tailor an advance directive to the particular health situation of concern. Compared with the "generic" approach of preprinted advance directive forms, a "disease-specific" approach is less hypothetical and can be based on more precise prognostic information.60 For instance, a physician caring for a patient with severe chronic obstructive pulmonary disease could draw the patient's attention to the issue of intubation and ventilation in the event of respiratory failure.

The physician can also ensure that the patient has correctly interpreted the information contained in a preprinted advance directive and is capable of completing it.[61,62]

Lawyers can make an important contribution by ensuring that an advance directive conforms to provincial legislation and is consistent with the patient's overall planning with regard to future

incapacity and death. (This may involve other matters such as designating power of attorney for finances and preparing an estate will.)

Research conducted at the University of Toronto Joint Centre for Bioethics has found that counseling is a valuable component of advance care planning. Whether such counseling is best performed by a physician, lawyer, nurse, social worker or other educator is unknown.

Physicians should suggest that patients review their advance care plans when their health status changes. This will help to ensure that the patient's preferences as expressed in an advance directive are current and likely to apply to future treatment decisions.

When the patient becomes incapable and his or her advance directive takes effect, the physician will seek consent to proceed with the proposed treatment plan from the substitute decision-maker appointed in the advance directive, as discussed in the previous article in this series.

**Cases revisited**

Mrs. Q is requesting information about advance care planning. Her physician should refer her to one of the available information sources and encourage her to begin the process of advance care planning with her preferred substitute decision-maker. After a period of time, Mrs. Q and her substitute might together meet with the physician. At this meeting, the physician can review Mrs. Q's treatment preferences to ensure that she has understood the information in the advance directive form and is capable of completing it. If Mrs. Q is concerned about the legal validity of her advance directive, the physician might recommend that she consult a lawyer. If her health situation changes, the physician should recommend that Mrs. Q update her advance directive.

Mr. R, unfortunately, may soon be incapable of making health care decisions. The physician should raise the subject of advance care planning with him in a sensitive manner and follow the same steps as described for Mrs. Q. However, in the case of Mr. R, the physician will have to pay particular attention to the issue of capacity. This situation also represents an opportunity for the physician to tailor the information considered by Mr. R in advance care planning to the likely future: progressive cognitive deterioration.

## Truth telling

**Abstract**

The standard of professional candor with patients has undergone a significant change over the past 30 years. Independent of their obligation to disclose information necessary for informed consent, physicians are increasingly expected to communicate important information to patients that is not immediately related to treatment decisions. The purpose of truth telling is not simply to enable patients to make informed choices about health care and other aspects of their lives but also to inform them about their situation. Truth telling fosters trust in the medical profession and rests on the respect owed to patients as persons. It also prevents harm, as

patients who are uninformed about their situation may fail to get medical help when they should.

Mr. S is 26 years old and has recently joined a family physician's practice. He had an episode last year of unilateral arm weakness and visual blurring without headache that resolved within 12 hours. He was referred to a neurologist, who did several tests. Mr. S was subsequently told not to worry about the episode and thought no more about it. He has had no similar episodes since. In his medical records is a letter from the neurologist to the previous family physician stating that Mr. S almost certainly has multiple sclerosis. In the letter the neurologist explains that in order to prevent excessive worry he does not inform patients in the early stages of multiple sclerosis of their diagnosis.

## What is truth telling?

In the practice of medicine, truth telling involves the provision of information not simply to enable patients to make informed choices about health care and other aspects of their lives but 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. Truth telling requires accuracy and honesty: as Cabot wrote at the turn of the century, physicians should strive to create a "true impression" in the mind of the patient.[1] Thus, truth telling requires that information be presented in such a way that it can be understood and applied. By contrast, deception involves intentionally leading another to adopt a belief that one holds to be untrue.[2]

## Why is truth telling important?

### Ethics

The covenant of trust between physician and patient is central to the practice of medicine.3 The candid disclosure and discussion of information not only helps patients to understand and deal with what is happening to them but also fosters and helps to maintain trust. Patients should be told the truth because of the respect due to them as persons. Patients have a right to be told important information that physicians have about them.

Not telling the truth can harm patients in many ways. Patients who remain uninformed about their condition may fail to obtain medical attention when they should. They may also make decisions affecting their lives that they would not make if they were aware of their condition. In addition, telling patients their diagnosis early in the course of a serious illness such as multiple sclerosis can be helpful simply because "some people find comfort in the knowledge that physicians can name their problem."[4]

Not telling patients the truth about their condition may entail deceiving them. Lack of candor or outright deception, even when well intentioned, can undermine the public's confidence in the medical profession.[5]

### Law

Legal aspects of physician–patient communication are discussed in earlier articles in this series (see sidebar). Truth telling goes beyond disclosure for the purpose of assisting the patient in making treatment decisions and includes the broader notion of the accurate and honest

communication of information. Canadian courts have dealt with lack of physician candor with regard to patient access to medical records, mishaps occurring in the course of treatment and the practice of "shielding" patients from bad news.

In discussing the right of patients to gain access to their own medical records, the Supreme Court of Canada acknowledged that information can have value to patients for its own sake and that "nondisclosure can itself affect the patient's well-being."[6] Good communication is required after treatment as well as before. For example, failure to tell a patient about the accidental puncture of his spleen during a lung biopsy was held to breach the physician's duty to inform the patient, particularly because the patient had asked what had occurred during the procedure. The judge concluded that litigation arose from a "less than satisfactory physician–patient relationship" precipitated by the lack of candid interchange following the mishap.[7]

A physician was found negligent in a case involving nondisclosure to the patient of his risk of having acquired HIV infection from a transfusion.[8] A family physician's desire "not to worry" a pregnant woman with information about serious but unlikely risks to the fetus after she contracted chicken pox proved an ineffective defense in a negligence action taken by the woman.[9]

Indeed, many legal actions result from communication difficulties between physicians and their patients.[10] Some patients who sue report having felt rushed or ignored during visits;[11] patients who are dealt with in this way are less likely to have their informational needs met than those who are given the time and opportunity to voice their concerns.[12] Effective and timely communication is essential to good care and can reduce the risk of malpractice claims.[13]

Physicians may be unsure whether to provide patients with statistics related to a prognosis. A court in California found no negligence in a physician's failure to disclose the precise statistical risk of death within 5 years to a patient with pancreatic cancer before the patient gave consent for experimental therapy. The court did not find, "as a matter of law," that any *particular* type of information must be disclosed, but it adhered to "the patient-based standard of disclosure" whereby "adequate information" must be given to enable the patient to make "an intelligent choice."[14]

The Supreme Court of Canada has granted that there may be narrow exceptions to truth telling, for example when the patient's emotional condition is such that the disclosure of bad news could cause harm.[15,16] The most relevant test for nondisclosure is "whether the disclosure would in itself cause physical and mental harm to *this* patient."[17] Physicians should start from the assumption that all patients are able to cope with the facts, and reserve nondisclosure for cases in which more harm will result from telling the truth than from not telling it.

**Policy**

The CMA Code of Ethics recommends that physicians provide patients with whatever information that will, from the patient's perspective, have a bearing on medical care decision-making and communicate that information in a way that is comprehensible to the patient.[18]

## Empirical studies

### Physicians

In a landmark study conducted in 1961, 90% of a sample of 219 US physicians reported that they would not disclose a diagnosis of cancer to a patient.[19] Of 264 physicians surveyed almost 20 years later, 97% stated that they would disclose a diagnosis of cancer.[20] This indicates a complete reversal of professional attitudes toward truth telling, at least in the context of a diagnosis of cancer.

Cultural values appear to influence physicians' attitudes toward truth telling. In one study, US physicians who reported that they commonly tell cancer patients the truth said that they did so in a way that was intended to preserve "hope" and "the will to live," both valued notions in US society.[21] The findings of another study suggested that gastroenterologists from southern and eastern Europe were less likely to be candid with patients than their North American counterparts.[22]

### Patients

The literature suggests that most patients want to be informed about their situation. For example, in a 1957 study involving 560 cancer patients and their families 87% of respondents felt that patients should be told the truth about their illness.[23] In a study done before any treatment existed for multiple sclerosis, many patients with the disease felt they had a right to know what was wrong with them. Some were angry about being asked why they wished to know. One wrote: "Do I have to explain why? Just so that I know."[24] A survey conducted in 1982 indicated that 94% of patients wanted to know everything about their condition, 96% wanted to be informed of a diagnosis of cancer and 85% wanted to be given a realistic estimate of their time to live, even if this were less than 1 year.[25] Other studies showed that over 90% of patients wanted to be told a diagnosis of Alzheimer disease[26] and that over 80% of patients with amyotrophic lateral sclerosis wanted to be given as much information as possible.[27]

Attitudes toward disclosure can vary from one cultural context to another. For example, in one study a greater percentage of Korean-born patients preferred to be given less information than did US-born patients.[28]

### Outcomes

Truth telling increases patient compliance,[29] reduces the morbidity such as pain[30] associated with medical interventions and improves health outcomes.[31] Informed patients are more satisfied with their care and less apt to change physicians than patients who are not well informed.[32]

Some studies suggest that truth telling can have negative consequences. For example, the diagnosis of hypertension may result in decreased emotional well-being and more frequent absence from work.[33]

**How should I approach truth telling in practice?**
Truth telling can be difficult in practice because of medical uncertainty and the concern that bad news might harm the patient. It can also be difficult when medical error occurs and when the patient's family is opposed to truth telling.

The pervasive uncertainty in medicine can and should be shared with patients.[34] Telling patients about the clinical uncertainties and the range of options available to them allows them to appreciate the complexities of medicine, to ask questions, to make informed, realistic decisions and to assume responsibility for those decisions.

Predicting what information a patient will find upsetting, or foreseeing *how* upsetting certain information will be, can be difficult. Patients may indicate, explicitly or implicitly,[35] their desire not to know the truth of their situation. When such desires are authentic they should be respected. It is possible to deliver the truth in a way that softens its impact; many books provide practical suggestions on telling bad news.[36,37] The truth may be brutal, but "the telling of it should not be."[38]

Physicians should disclose the occurrence of adverse events or errors to patients but should not suggest that they resulted from negligence. The admission of error is not an admission of substandard practice. Negligence is a finding made in court, not by physicians or their colleagues.

Telling the truth can defuse resentment on the part of the patient and reduce the risk of legal action.[39] People sometimes sue physicians out of a "need for explanation -- to know how the injury happened and why."[40] Truth telling at the time of the misadventure can ensure that an injured patient seeks appropriate corrective treatment promptly. Such frankness may thus foster, rather than undermine, the patient's trust in physicians.

In some cultural settings patients with terminal illnesses may waive their right to know about their situation or transfer that right to family members.[41] Physicians should explore such waivers sensitively with their patients to ascertain whether they are authentic requests. Patients should be explicitly offered the opportunity to be told important information.[42] When a patient has a serious illness such as cancer, it may be helpful to document his or her preferences regarding the involvement of family members. Families who resist disclosure of the truth should be counseled about the importance of truth telling, much as they might be counseled about the appropriate management of any medical problem.

It is important to bear in mind that substantial variability exists within cultures and that cultural values can change. For example, in Japan, where medicine has traditionally been very paternalistic,[43] the National Cancer Centre decided in 1995 that cancer patients must be given a form describing their disease and various side-effects of treatment.[44]

**The case**

If the neurologist seriously considered multiple sclerosis as a likely or working diagnosis he was not justified in withholding this information from Mr. S. A general worry about causing

anxiety is not sufficient to exempt a physician from his responsibility to tell the patient the truth. Physicians need not and should not wait for near certainty before they disclose information to patients. If Mr. S is not told about his condition and makes a decision that he would not otherwise have made, his physicians would bear some moral responsibility and even legal liability for any untoward outcome that resulted. Likewise, Mr. S's physicians could be held responsible if he failed to avail himself of new and potentially beneficial treatments[45] were his condition to worsen.

## Confidentiality

### Abstract

Physicians are obliged to keep information about their patients secret. The understanding that the physician will not disclose private information about the patient provides a foundation for trust in the therapeutic relationship. Respect for confidentiality is firmly established in codes of ethics and in law. It is sometimes necessary, however, for physicians to breach confidentiality. Physicians should familiarize themselves with legislation in their own province governing the disclosure of certain kinds of information without the patient's authorization. Even when no specific legislation applies, the duty to warn sometimes overrides the duty to respect confidentiality. The physician should disclose only that information necessary to prevent harm, and should reveal this information only to those who need to know it in order to avert harm. Whenever possible any breach of confidentiality should be discussed with the patient beforehand.

Mr. T is 35 years old and is married. He has had unprotected sex with prostitutes on 2 occasions. Although he is asymptomatic, he becomes anxious about the possibility of having contracted a venereal disease and consults his physician. After conducting a thorough physical examination and providing appropriate counseling, Mr. T's physician orders a number of tests. The only positive result is for the HIV blood test. The physician offers to meet with Mr. T and his wife to assist with the disclosure of this information, but Mr. T states that he does not want his wife to know about his condition.

Mr. U is a 42-year-old professional who is living with his 14-year-old son and is involved in an acrimonious divorce. He is receiving drug therapy and weekly psychotherapy sessions for depression. Mr. U tells his psychiatrist that his wife makes him so crazy that at times he wants to kill her. He is concerned that in the heat of a confrontation he might act on this impulse. However, he recognizes that killing his wife would be devastating to his son, for whom he feels a great deal of affection and devotion.

Ms. V is 29 years old and has epilepsy. Her driver's license was revoked when the ministry of transportation was notified of her history of seizures. Ms. V mentions in passing to her physician that she sometimes drives short distances to get groceries with her 3-year-old daughter in the car. When the physician challenges her about this, Ms. V emphasizes that her

seizures are very infrequent. Finally, the physician states that he might be obliged to notify the authorities. Ms. V asks what more the authorities could do, now that they have revoked her license. Would they put a police cruiser outside her house to make sure she doesn't drive?

**What is confidentiality?**
Physicians are obliged to keep information about their patients confidential. Confidentiality provides a foundation for trust in the therapeutic relationship.

**Why is confidentiality important?**

**Ethics**

Without an understanding that their disclosures will be kept secret, patients may withhold personal information. This can hinder physicians in their efforts to provide effective interventions or to pursue certain public health goals. For example, some patients may not feel secure in confiding a drug or alcohol dependence and thus may not have the benefit of treatment. Others may refrain from disclosing information that could alert the physician to the potential for harm or violence to others.

Respect for the confidentiality of patient information is not based solely on therapeutic considerations or social utility, however. Of equal, if not greater, importance is the physician's duty to respect patient autonomy in medical decision-making. Competent patients have the right to control the use of information pertaining to themselves. They have the right to determine the time and manner in which sensitive information is revealed to family members, friends and others.

In our strongly individualistic society the principle of autonomy is taken very seriously. This principle, however, is not absolute. As John Stuart Mill observed in the 19th century, personal freedom may legitimately be constrained when the exercise of such freedom places others at risk:

> [T]he sole end for which mankind are warranted, individually or collectively, in interfering with the liberty of action of any of their number, is self-protection . . . [T]he only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others.[1]

Applied to the question of confidentiality, this suggests that although patients have the right to control how information about themselves is shared, this right is limited by the obligation not to harm others. When harm is threatened, the principle of autonomy (and hence the duty to preserve confidentiality) no longer takes precedence, and disclosure without the patient's authorization may be permissible or required.

**Law**

The confidentiality of patient information is prescribed in law. For example, physicians in Ontario are prohibited from providing information to third parties regarding a patient's condition or any professional service performed for a patient without the consent of the patient

or his or her authorized agent unless such disclosure is required by law.[2] A breach of confidentiality that is not required by law may prompt disciplinary action by the College of Physicians and Surgeons of Ontario. Similar provisions concerning confidentiality exist in other provinces. Moreover, a breach of confidentiality may result in a civil suit.

Legal requirements to reveal certain kinds of information without the patient's consent are defined in both statutory and common law. The most notable legislated requirement involves the mandatory reporting of patients who suffer from designated diseases, those deemed not fit to drive and those suspected of child abuse.[3]

The case of *Tarasoff* v. *Regents of the University of California*[4,5] involved a psychologist who had reason to believe that his patient would kill a woman named Ms. Tarasoff. At the psychologist's request the campus police arrested the patient, but he was released when he assured the police that he would stay away from Tarasoff. No further action was taken, and the patient killed Tarasoff 2 months later.[4] Two decisions resulted from this case. The first established the duty to warn.[4] The American Psychiatric Association lobbied for the case to be reheard by the California Supreme Court.[6] As a result, a duty to protect was established that may or may not include a warning to the potential victim or the police.[5] The decision also implied that committing a dangerous patient to institutional care would obviate the need to warn.

Although the Tarasoff decision does not impose a legal duty upon Canadian physicians it could reasonably be expected that Canadian courts would apply similar reasoning in a comparable case. In *Tanner* v. *Norys* the Alberta Court of Appeal stated that if it were presented with a case involving a psychiatrist who failed to warn another of the risk of harm, then it would follow the reasoning used in the Tarasoff case.[7] In the report of the Commission of Inquiry into the Confidentiality of Health Information, Justice Horace Krever wrote that "it cannot be said with certainty that an Ontario court would decide a case involving identical circumstances [to those in *Tarasoff*] in a different way."[8]

Most recently, the College of Physicians and Surgeons of Ontario accepted recommendations formulated by an expert panel representing provincial and national medical organizations. The panel determined that physicians have a duty to warn when a patient reveals that he or she intends to do serious harm to someone else and it is more likely than not that this intention will be carried out.[9] The college has recommended that a standard of practice be established such that failure to warn would become a basis for a disciplinary finding of professional misconduct.[10] This recommendation, although accepted, has yet to be implemented and has not yet been adopted in law.

**Policy**

The Hippocratic Oath[11] explicitly demands confidentiality in physicians' dealings with patients:

> What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread

> abroad, I will keep to myself holding such things shameful to be spoken about.[11]

The Hippocratic Oath and subsequent codes of ethics[12] admitted no exceptions to the duty of confidentiality. However, more recent codes allow that breaches of confidentiality may be justified or required in certain circumstances. For example, the CMA Code of Ethics states:

> 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.[13]

Thus, according to the CMA Code of Ethics, physicians may disclose confidential information not only when they are required to do so by law but also when there is significant risk of substantial harm to others (which is, in effect, the reasoning underlying any legal duty to warn). The CMA position statement on AIDS advises physicians that

> disclosure to a spouse or current sexual partner may not be unethical and, indeed, may be indicated when physicians are confronted with an HIV-infected patient who is unwilling to inform the person at risk. Such disclosure may be justified when all of the following conditions are met: the partner is at risk of infection with HIV and has no other reasonable means of knowing the risk; the patient has refused to inform his or her sexual partner; the patient has refused an offer of assistance by the physician to do so on the patient's behalf; and the physician has informed the patient of his or her intention to disclose the information to the partner.[14]

The CMA has affirmed that medical records are confidential documents and that patient authorization is necessary for the disclosure of information contained in such records to a third party, unless such disclosure is required by law. Although medical records are the property of the physician or health care institution that compiled them, patients have the right to examine their records and to copy the information they contain.[15]

The Canadian Psychiatric Association[16] recommends that patients whom a physician believes at any point during treatment to be dangerous or potentially dangerous should be informed that confidentiality may be breached for his or her own protection and that of any potential victim. The association also recommends that any breach of confidentiality should be discussed beforehand and that the patient's cooperation should be enlisted if possible.

**Empirical studies**

Farber and associates[17] found that internal medicine residents based their decisions to breach confidentiality on factors other than the patient's intention to commit specific acts of violence. Reports of past violence, a criminal record and a history of high-cost crime increased the likelihood that confidential information would be disclosed. Cheng and collaborators[18] found that most adolescents who responded to their survey had problems that they wished to be kept

secret and would not seek the help of health care professionals because of concerns about confidentiality. Ubel and colleagues[19] reported that inappropriate comments were made by hospital staff on 14% of elevator rides in the 5 institutions studied. Most frequently, these remarks constituted a breach of patient confidentiality.

**How should I approach confidentiality in practice?**

Physicans must respect their patient's confidences. Private information should be revealed to a third party only with the consent of the patient or his or her authorized representatives or when required by law.

Physicians should familiarize themselves with the legal requirements in their own province for the disclosure of patient information. When possible, it is important to discuss with the patient the necessity of any disclosure before it occurs and to enlist his or her cooperation. For example, it is helpful to persuade a patient suspected of child abuse to call the Children's Aid Society in the physician's presence to self-report, or to obtain his or her consent before the authorities are notified. This approach will prepare the way for subsequent interventions.

When harm is threatened and there is no specific legal requirement for disclosure the duty to warn may still override the duty to respect confidentiality. This is the case when the anticipated harm is believed to be imminent, serious (and irreversible), unavoidable except by unauthorized disclosure, and proportionate to the harm likely to result from disclosure. In determining the proportionality of these respective harms, the physician must assess and compare the seriousness of the harms and the likelihood of their occurrence. In all instances, but particularly when the harms appear equal, the physician must exercise his or her judgment. In cases of doubt, it would be prudent for the physician to seek expert advice, such as from the Canadian Medical Protective Association, before breaching confidentiality.

When a physician has determined that the duty to warn justifies an unauthorized disclosure, two further decisions must be made. Whom should the physician tell? How much should be told? Generally speaking, the disclosure should contain only that information necessary to prevent the anticipated harm and should be directed only to those who need the information in order to avert the harm. Reasonable steps should be taken to mitigate the harm and offense to the patient that may arise from the disclosure.

**The cases**

Mr. T's physician warns him that steps will have to be taken to ensure that his wife is made aware of his condition. These steps might include a direct warning to his wife and notification of the public health department. The physician subsequently decides to enlist the help of the department, which she believes to be experienced in dealing with this kind of issue. The public health authorities contact Mr. T and tell him that he must inform his wife. Mr. T responds to their authority and brings his wife to see his physician to be told about his condition.

Mr. U's psychiatrist carefully assesses the homicidal potential of his patient and concludes that Mr. U's wife is in no imminent danger. Mr. U does not really want to kill her and has never had violent outbursts in the past. More important, he does not want his son to suffer the negative consequences of such an action. Given the hostility he feels, Mr. U resolves to avoid contact

with his wife. Psychotherapy continues, addressing a number of issues. A settlement with the wife is reached and Mr. U becomes involved in another relationship.

Ms. V's physician seeks legal advice to determine his obligations. He receives conflicting opinions. One opinion states that a duty to inform under these circumstances exists under the province's highway traffic act. A written opinion from the ministry of transportation states that once medical evidence has been received and action has been taken to suspend the driver's license, further notification is not necessary. The relevant health care legislation permits confidentiality to be breached only when this is required by law.

This raises the question of whether the reasoning used in the Tarasoff case would apply, such that the physician has a duty to warn. The patient has had only 1 or 2 seizures during the past year and feels that she can tell when they are coming on. At most, she drives for 5 minutes 2 to 3 times per week. The probability of an accident resulting in serious irreversible harm is therefore very low. Furthermore, it is not clear that anyone is in a position to intervene even if notification were made.

Ms. V's physician feels that his patient is denying the reality of her illness and does not appreciate the risks involved. Over the next 2 weeks he continues to counsel her, explaining the risks to her daughter, to other people and to herself, given that she probably would not be insured in the event of an accident. This proves effective in penetrating Ms. V's denial of her illness. She tells the physician that she has decided not to drive again while her license is revoked. Ms. V continues to work with her physician, addressing other areas of her life. This case highlights the importance of continuing to work therapeutically with patients while considering ethical and legal concerns.

## Involving children in medical decisions

### Abstract

Medical decisions involving children raise particular ethical issues for physicians and other members of the health care team. Although parents and physicians have traditionally made most medical decisions on behalf of children, the developing autonomy of children is increasingly being recognized in medical decision-making. This poses a challenge for physicians, who must work with the child's family and with other health care practitioners to determine the child's role in decision-making. A family-centered approach respects the complex nature of parent–child relationships, the dependence and vulnerability of the child and the child's developing capacity for decision-making.

### Introduction

Eleven-year-old Samantha is a bright, loving child who was treated for osteosarcoma in her left arm. The arm had to be amputated, and Samantha was given a course of chemotherapy. She

has been cancer-free for 18 months and is doing well in school. She is self-conscious about her prosthesis and sad because she had to give away her cat, Snowy, to decrease her risk of infection. Recent tests indicate that the cancer has recurred and metastasized to her lungs. Her family is devastated by this news but do not want to give up hope. However, even with aggressive treatment Samantha's chances for recovery are less than 20%.

Samantha adamantly refuses further treatment. On earlier occasions she had acquiesced to treatment only to struggle violently when it was administered. She distrusts her health care providers and is angry with them and her parents. She protests, "You already made me give up Snowy and my arm. What more do you want?" Her parents insist that treatment must continue. At the request of her physician, a psychologist and psychiatrist conduct a capacity assessment. They agree that Samantha is probably incapable of making treatment decisions; her understanding of death is immature and her anxiety level very high. Nursing staff are reluctant to impose treatment; in the past Samantha's struggling and the need to restrain her upset them a great deal.

## Why is it important to include children in medical decision-making?

### Ethics

Traditionally, parents and physicians have made all medical decisions on behalf of children. However, just as the concept of informed consent has developed over the last 30 years with respect to competent adult patients, so new ways of thinking about the role of children in medical decision-making have evolved.

Ethical principles that provide guidance in the care of adults are insufficient in the context of caring for children.[1–3] Issues related to the voluntariness of consent, the disclosure of information, capacity assessment, treatment decisions and bereavement are more complex, as is the physician's relationship with the patient and the patient's family.[3,4] Adult models presume that the patient is autonomous and has a stable sense of self, established values and mature cognitive skills; these characteristics are undeveloped or underdeveloped in children.

Although it is important to understand and respect the developing autonomy of a child, and although the duty of beneficence provides a starting point for determining what is in the child's best interest, a family-centered ethic is the best model for understanding the interdependent relationships that bear upon the child's situation.[5] A family-centered approach considers the effects of a decision on all family members, their responsibilities toward one another and the burdens and benefits of a decision for each member, while acknowledging the special vulnerability of the child patient.

A family-centered approach presents special challenges for the health care team, particularly when there is disagreement between parent and child. Such a situation raises profound questions about the nature of the physician–patient relationship in pediatric practice. Integrity in this relationship is fundamental to the achievement of the goal of medicine,[6] which has been defined as "right and good healing action taken in the interest of a particular patient."[7] In the care of adults, the physician's primary relationship is with the particular capable patient. The patient's family may be involved in decision-making, but it is usually the patient who defines the bounds of such involvement.

The care of children, on the other hand, has been described in terms of a "triadic" relationship in which the child, his or her parents and the physician all have a necessary involvement (Dr. Abbyann Lynch, Director, Ethics in Health Care Associates, Toronto: personal communication, 1992). When there is disagreement between parent and child, the physician may experience some moral discomfort in having to deal separately with the child and parent.

The assumption that parents best understand what is in the interest of their child is usually sound. However, situations can arise in which the parents' distress prevents them from attending carefully to the child's concerns and wishes. Simply complying with the parents' wishes in such cases is inadequate. It is more helpful and respectful of the child to affirm the parents' responsibility for the care of their child while allowing the child to exercise choice in a measure appropriate to his or her level of development and experience of illness and treatment. This approach does not discount the parents' concerns and wishes, but recognizes the child as the particular patient to whom the physician has a primary duty of care. This approach seeks to harmonize the values of everyone involved in making the decision.[6]

**Law**

The legal right to refuse medical treatment is related to, but not identical with, the right to consent to treatment. The patient's right to refuse even life-saving medical treatment is recognized in Canadian law[8,9] and is premised on the patient's right to exercise control over his or her own body. Providing treatment despite a patient's valid refusal can constitute battery and, in some circumstances, negligence.

To be legally valid the refusal of medical treatment must be given by a person deemed capable of making health care choices, that is, capable of understanding the nature and consequences of the recommended treatment, alternative treatments and nontreatment. In common law the notion of the "mature minor" recognizes that some children are capable of making their own health care choices despite their age.[10] In common law and under the statutory law of some provinces patients are presumed capable regardless of age unless shown otherwise; in other provinces an age at which patients are presumed capable is specified.[11] When a child's capacity is in doubt an assessment is required.

In the case of children who are incapable of making their own health care decisions, parents or legal guardians generally have the legal authority to act as surrogate decision-makers. The surrogate decision-maker is obliged to make treatment decisions in the best interest of the child. Health care providers who believe that a surrogate's decisions are not in the child's best interest can appeal to provincial child welfare authorities. The courts have the authority to assume a *parens patriae* role in treatment decisions if the child is deemed to be in need of protection. This issue has arisen most commonly with respect to Jehovah's Witnesses who refuse blood transfusions for their children on religious grounds, and courts have authorized treatment in recognition of the state's interest in protecting the health and well-being of children.[12] Every province has child welfare legislation that sets out the general parameters of the "best interest" standard. Courts are reluctant to authorize the withholding or withdrawal of medical treatment, especially in the face of parental support for such treatment.

A special point to consider involves the use of patient restraints. The wrongful or excessive use of restraints could prompt an action of false imprisonment or battery. Restraint can involve the use of force, mechanical means or chemicals. The use of restraint compromises the dignity and liberty of the patient, including the child patient. Restraints should never be used solely to facilitate care but, rather, only when the patient is likely to cause serious bodily harm to himself or herself or to another. If restraint is required, the health care provider should use the least restrictive means possible, and the need for the restraint (as well as its effect on the patient) should be assessed on an ongoing basis.

### Policy

The Canadian Paediatric Society has no policy regarding the role of the child patient in medical decision-making. The American Academy of Pediatrics statement on this question articulates the joint responsibility of physicians and parents to make decisions for very young patients in their best interest and states that "[p]arents and physicians should not exclude children and adolescents from decision-making without persuasive reasons."[13]

### Empirical studies

As they grow, children develop decision-making skills, the ability to reason using complex concepts, an understanding of death[14] and the ability to imagine a future for themselves.[15] Children with a chronic or terminal illness may have experiences that endow them with insight and maturity beyond their years. Families often encourage children to participate in decision-making. Allowing even young children to make decisions about simple matters facilitates the development of skills that they will need to make more complex decisions later on.[16–18]

Because tools developed to assess the capacity of adults have not been tested with children, health care professionals working with children should be sensitive to the particular capacity of each child. Children are constantly developing their physical, intellectual, emotional and personal maturity. Although developmental milestones give us a general sense of capacities, 2 children of the same age will not necessarily have the same ability to make choices. Even when they are deemed capable of making health care choices, children need support for their decisions from family members and the health care team.

## How should I determine the appropriate role of a child in medical decision-making?

Most children fall into one of three groups with respect to their appropriate involvement in decision-making.[19,20]

### Infants and young children

Preschool children have no significant decision-making capacity and cannot provide their own consent. As surrogate decision-makers, parents should authorize (or refuse authorization) on their child's behalf, basing their decisions on what they believe to be in the child's best interest.

### Primary-school children

Children of primary-school age may participate in medical decisions but do not have full decision-making capacity. They may indicate their assent or dissent without fully understanding its implications. Nonetheless they should be provided with information

appropriate to their level of comprehension. Although the child's parents should authorize or refuse to authorize treatment, the child's assent should be sought and any strong and sustained dissent should be taken seriously.[21]

**Adolescents**

Many adolescents have the decision-making capacity of an adult.[22,23] This capacity will need to be determined for each patient in light of his or her

- ability to understand and communicate relevant information,
- ability to think and choose with some degree of independence,
- ability to assess the potential for benefit, risks or harms as well as to consider consequences and multiple options, and
- achievement of a fairly stable set of values.[24]

Many children and adolescents, particularly those who have been seriously ill, will need assistance in developing an understanding of the issues and in demonstrating their decision-making capacity. Age-appropriate discussions, perhaps with the assistance of teachers, chaplains, play therapists, nurses, psychologists or others skilled in communicating with children, are helpful. The child's participation may be facilitated by the use of art activities, stories, poems, role-playing and other techniques.[25,26]

Physicians should ensure that good decisions are made on behalf of their child patients. Although the interests of other family members are important and will influence decision-making, the child's interests are most important and are unlikely to be expressed or defended by the child himself or herself. Anxious, stressed or grieving family members may need assistance in focusing on what is best for the child. This may be especially difficult when a cure is no longer possible; in such cases a decision to stop treatment may seem like a decision to cause the child's death.

Whether or not the child participates, the following considerations should bear upon a treatment decision concerning that child:

- The potential benefits to the child
- The potential harmful consequences to the child, including physical suffering, psychological or spiritual distress and death
- The moral, spiritual and cultural values of the child's family

**The case**

For Samantha, resuming aggressive treatment will have a serious negative effect on her quality of life. The chances of remission are small, yet a decision to discontinue treatment will likely result in her death. Because death is an irreversible harm, and decisions with serious consequences require a high level of competence in decision-making,[27] the capacity required would be very high. It has been determined that Samantha does not have this capacity.

Nevertheless, Samantha is included in discussions about her treatment options, and her reasons for refusing treatment are explored.[28] Members of the team work hard to re-establish trust.

They and Samantha's parents come to agree that refusing treatment is not necessarily unreasonable; a decision by an adult patient in similar circumstances to discontinue treatment would certainly be honored. Discussions address Samantha's and her parents' hopes and fears, their understanding of the possibility of cure, the meaning for them of the statistics provided by the physicians, Samantha's role in decision-making and her access to information. They are assisted by nurses, a child psychologist, a psychiatrist, a member of the clergy, a bioethicist, a social worker and a palliative care specialist.

Discussions focus on reaching a common understanding about the goals of treatment for Samantha. Her physician helps her to express her feelings and concerns about the likely effects of continued treatment. Consideration is given to the effects on her physical well-being, quality of life, self-esteem and dignity of imposing treatment against her wishes. Spiritual and psychological support for Samantha and her family is acknowledged to be an essential component of the treatment plan. Opportunities are provided for Samantha and her family to speak to others who have had similar experiences, and staff are given the opportunity to voice their concerns.

Ultimately, a decision is reached to discontinue chemotherapy and the goal of treatment shifts from "cure" to "care." Samantha's caregivers assure her and her family that they are not "giving up" but are directing their efforts toward Samantha's physical comfort and her spiritual and psychological needs. Samantha returns home, supported by a community palliative care program, and is allowed to have a new kitten. She dies peacefully.

## Research ethics

### Abstract

Medical research involving human subjects raises complex ethical, legal and social issues. Investigators sometimes find that their obligations with respect to a research project come into conflict with their obligations to individual patients. The ethical conduct of research rests on 3 guiding principles: respect for persons, beneficence, and justice. Respect for persons underlies the duty to obtain informed consent from study participants. Beneficence demands a favorable balance between the potential benefits and harms of participation. Justice requires that vulnerable people not be exploited and that eligible candidates who may benefit from participation not be excluded without good cause. Studies must be designed in a way that ensures the validity of findings and must address questions of sufficient importance to justify the risks of participation. In any clinical trial there must be genuine uncertainty as to which treatment arm offers the most benefit, and placebo controls should not be used if effective standard therapies exist. Researchers have a responsibility to inform themselves about the ethical, legal and policy standards that govern their activities. When difficulties arise, they should consult the existing literature and seek the advice of experts in research ethics.

## Introduction

Dr. W is a family practitioner with a special interest in the treatment of HIV infection and AIDS. He receives a letter from the coordinator of a study to evaluate a promising new treatment for the prevention of HIV-related dementia. The letter invites Dr. W to submit the names of potentially eligible patients. He will be paid $100 for each name provided.

Dr. X, a psychiatrist in private practice, is approached by a pharmaceutical company to assist with a clinical trial to test the efficacy of a new drug in the treatment of acute psychosis. The study will enroll acutely psychotic patients with no history of psychosis (or of treatment with antipsychotic drugs) through physicians' offices and emergency departments. Patients enrolled in the study will be randomly assigned to receive the new medication or a placebo and will remain in hospital for 8 weeks. During this time they will not be permitted to receive antipsychotic medications other than the study drug. Informed consent will be obtained from each participant or a proxy. Patients may be withdrawn from the study if their medical condition worsens substantially.

### What is research ethics?

Research involving human subjects can raise difficult and important ethical and legal questions. The field of research ethics is devoted to the systematic analysis of such questions to ensure that study participants are protected and, ultimately, that clinical research is conducted in a way that serves the needs of such participants and of society as a whole.

### Why is research ethics important?

Many of the ethical issues that arise in human experimentation -- such as those surrounding informed consent, confidentiality and the physician's duty of care to the patient -- overlap with ethical issues in clinical practice. Nevertheless, important differences exist between research activities and clinical practice. In clinical practice, the physician has a clear obligation to the patient; in research, this obligation remains but may come into conflict with other obligations -- and incentives.[1] The researcher has an obligation to ensure that the study findings are valid and replicable, and this has implications for the design and execution of the study. For example, the study must be designed in such a way that the research question is answered reliably and efficiently; sufficient numbers of patients must be enrolled in a reasonable period; and study participants must comply with their allocated treatment. Substantial rewards can accrue to the successful completion of a research project, such as renewed funding, academic promotion, salary increases, respect from colleagues and, in some cases, fame. Unfortunately, in a number of research studies, including some conducted in Canada, the welfare of individual patients has been sacrificed to these competing interests.[2,3] Various ethical principles, legal requirements and policy statements have been formulated in an attempt to ensure that clinical research is conducted in accordance with the highest scientific and ethical standards.

## Ethics

The predominant ethical framework for human experimentation was set out by the US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in

the Belmont Report.[4] This report articulated 3 guiding principles for research: respect for persons, beneficence, and justice. Respect for persons requires that the choices of autonomous individuals be respected and that people who are incapable of making their own choices be protected. This principle underlies the requirement to obtain informed consent from study participants and to maintain confidentiality on their behalf.[5] The principle of beneficence requires that participation in research be associated with a favorable balance of potential benefits and harms.[6] The principle of justice entails an equitable distribution of the burdens and benefits of research. Researchers must not exploit vulnerable people or exclude without good reason eligible candidates who may benefit from participation in a study.[7]

The principles set out in the Belmont Report do not, however, exhaust the ethical requirements for clinical research.[8] Conditions such as the following must also be met.

- A study must employ a *scientifically valid design* to answer the research question. Shoddy science is never ethical.[9,10]
- 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.[9]
- A study must be *conducted honestly*. It should be carried out as stated in the approved protocol, and research ethics boards have an obligation to ensure that this is the case.[11]
- Study findings must be *reported accurately and promptly*. Methods, results and conclusions must be reported completely and without exaggeration to allow practicing clinicians to draw reasonable conclusions.[12,13] Whenever possible, study results should be reported quickly to allow physicians timely access to potentially important clinical information.[14]

**Law**

The researcher's duty to have informed consent from research subjects is established in law. The legal doctrine often described as "informed consent" is better understood as "informed choice," since a physician's legal duty is to inform the patient so that he or she may exercise *choice* -- which does not always result in *consent*. The physician's duty to disclose information relevant to the choice that the patient is asked to make falls under an aspect of civil law: the law of negligence. A physician may be found negligent if a patient's choice (including the choice to forgo treatment) is inadequately informed and results in harm.[15] Accordingly, patients who are invited to enter a study must be informed of, among other things, the nature and extent of the known risks of participation, the possibility that participation may present unknown risks, and the intended benefit of the study to participants and others. A subject's treatment in a trial without consent may be grounds for legal action on the basis of "unauthorized touching," which is dealt with in 2 domains: assault in criminal law, and battery in civil law.

The duty to ensure confidentiality is founded in the physician–patient contract, fiduciary duty and legislation. Confidentiality is a usually implicit term of the physician–patient contract (that is, the tacit agreement between physician and patient on the rendering of care), and its violation is therefore a basis for legal action against the physician. Increasingly, however, as physicians

move from fee-for-service payment to salaries or other remuneration systems, confidentiality is addressed under the law of fiduciary duty.[16] Fiduciary duty -- the highest standard of duty implied by law -- requires that physicians disclose information about a patient only in the patient's best interests and that they avoid any conflict of interest in the disclosure of patient information (even if that information is contained in records physicians lawfully hold). Unauthorized disclosure is actionable as a breach of fiduciary duty. It may also violate a duty of confidentiality enacted in provincial legislation (which varies substantially from province to province). For example, the Civil Code of Quebec is so protective of patient information that anonymous epidemiologic studies may be unlawful without the consent of each person whose medical record is used.[17]

**Policy**

A number of international policies guide the conduct of research. Although the Nuremberg Code and the International Covenant on Civil and Political Rights remain important early statements,[18,19] the World Medical Association's Declaration of Helsinki, as amended most recently in October 1996, is probably the most influential document governing research world wide.[12] Many of the requirements set out under "Ethics" in this article reflect the Declaration of Helsinki. The Declaration highlights an important additional requirement: patients' participation in research should not put them at a disadvantage with respect to medical care.

Canadian researchers conducting studies funded by the US National Institutes of Health must do so in accordance with the regulations of the US Department of Health and Human Services.[20] Researchers conducting research in other countries should consult the guidelines of the Council for International Organizations of Medical Sciences.[21,22] Geneticists should consult the guidelines developed by the Human Genome Organization.[23]

Medical research in Canada, including studies conducted in the drug approval process, is governed by guidelines of the Medical Research Council (MRC) of Canada.[24,25] These guidelines define research as "the generation of data about persons, through intervention or otherwise, that goes beyond that necessary for the individual person's immediate well being."[24] Proposals for research involving human subjects must be submitted to a local research ethics board for review. Research that will not generate generalizable knowledge (e.g., quality assurance research for internal use and not intended for publication) is generally considered exempt from such review.

The Tri-Council Working Group, a collaboration of the MRC, the Natural Sciences and Engineering Research Council of Canada and the Social Sciences and Humanities Research Council of Canada, is preparing the final version of its code of conduct for research involving humans. A draft document, released in March 1996, generated considerable interest and controversy.[26] It proposed important new standards with respect to research involving communities or "collectivities" (including a requirement to involve community members, where appropriate, in the design process) and the inclusion of women (including "potentially pregnant" and pregnant women) in clinical studies. It also proposed the clear prohibition of placebo-controlled studies when effective standard treatment exists. If the final version closely resembles the draft document in these respects, substantial changes in the conduct of research in Canada will ensue.

**Empirical studies**

Empirical studies have much to contribute to our understanding of informed consent and the risks and benefits of participation in research. For example, if the principle of respect for persons is to be upheld, it follows that research subjects must not only be *informed* of the purpose, nature, risks, benefits and alternatives associated with their participation but must also *understand* this information. But how well *do* research subjects understand information presented to them in the consent process? The answer seems to be "Not well at all."[27] Indeed, because of a phenomenon that Appelbaum and colleagues[28] refer to as "therapeutic misconception," patients commonly believe that experimental projects are tailored to optimize their individual care. In its final report, the White House Advisory Committee on Human Radiation Experiments detailed the results of a survey of 1900 research participants and concluded that serious deficiencies remain in the current system of protecting human subjects of research.[29]

Two lessons follow from the empirical studies on informed consent to participation in research. First, researchers need to establish and maintain effective strategies to ensure that research subjects comprehend the information they are given during the consent process. In an elegant review of this topic, Silva and Sorrell list a wide range of methods available to improve participants' understanding.[30] Second, although such additional measures are important, the empirical data highlight the inadequacy of consent alone to protect study participants. Consent is an important component of this protection, but a research study must present an acceptable balance of risks and benefits as well.[31]

Empirical studies on the risks and benefits of research participation have also made an important contribution to research ethics. For many years, participation in research was viewed as a risky endeavor, one from which people ought to be protected.[32] However, a number of studies in the late 1970s and early 1980s showed that the risks associated with study participation were, in reality, relatively small.[33] Indeed, recent empirical work in oncology suggests that cancer patients who participated in clinical trials received -- apart from the specific study treatment -- a *net benefit*, namely, improved survival.[34–37] If further study establishes conclusively that trial participation *in itself* is associated with a higher probability of benefit, it may be that prospective study participants should be informed of this fact.

**How should I approach research ethics in practice?**

Ethical issues in research must not be addressed by researchers as an afterthought. Ethical issues permeate research and must guide research design. What should be used as a control treatment? Who should be included or excluded from a study? How large should the sample be? All of these questions have an ethical component.[38] Researchers ought, therefore, to consider ethical issues from the first stages of planning.

What resources are available to researchers to guide them in ethical matters? Clearly, all Canadian physicians involved in research ought to be familiar with the key documents outlined earlier, particularly the MRC guidelines (and the Tri-Council guidelines when they become available). Though directed primarily toward an American audience, a number of excellent reference texts are available.[5,39] To our knowledge, the only peer-reviewed journal devoted exclusively to research ethics is *IRB: A Review of Human Subjects Research* -- an excellent

source for the researcher in an ethical quandary. Finally, and perhaps most important, clinicians should routinely consult with colleagues who have expertise in the ethics of research, including members of research ethics boards.

**The cases**

Dr. W is offered a financial reward if he will provide the names of patients to a third party who is coordinating a research study. Such "finders' fees" are ethically and legally objectionable.[40] Physicians act in breach of fiduciary duty and in conflict of interest if they use their professional knowledge of a patient's medical or other circumstances for their personal benefit. First, names may not be given to third parties without patient consent. A physician who believes that entry in a study may benefit an eligible patient should inform that patient and let the patient decide whether his or her name may be given to the investigator. Second, physicians must not accept a fee based on the number of names provided. If a physician 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, whether or not any patients are identified and consent to participate.

Dr. X is invited to enroll his patients in a placebo-controlled study of a new antipsychotic drug. Is it ethical for him to recommend the study to his patients? No. As we have discussed, consent alone is an insufficient ethical basis for enrolling patients in a study: the study must present a favorable balance of benefits and harms. A physician may recommend participation in a study only if the treatments being studied are in a state of "clinical equipoise," that is, if there is "genuine uncertainty" within "the expert clinical community about the comparative merits of the alternatives to be tested."[41] In other words, genuine uncertainty must exist in the community of expert practitioners as to the preferred treatment.[41] When effective standard treatment exists for a disease, as it does for schizophrenia,[42] it is unethical (since placebo is an inferior "treatment") to expose patients to the risk of "treatment" with placebo alone. Practicing physicians may be told that placebo controls are necessary in clinical research for scientific, ethical or regulatory reasons. Freedman and colleagues have reviewed these claims comprehensively and conclude that practitioners should regard them with skepticism.[43,44]

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## Euthanasia and assisted suicide

**Abstract**

Euthanasia and assisted suicide involve taking deliberate action to end or assist in ending the life of another person on compassionate grounds. There is considerable disagreement about the acceptability of these acts and about whether they are ethically distinct from decisions to forgo life-sustaining treatment. Euthanasia and assisted suicide are punishable offences under

Canadian criminal law, despite increasing public pressure for a more permissive policy. Some Canadian physicians would be willing to practice euthanasia and assisted suicide if these acts were legal. In practice, physicians must differentiate between respecting competent decisions to forgo treatment, providing appropriate palliative care, and acceding to a request for euthanasia or assisted suicide. Physicians who believe that euthanasia and assisted suicide should be legally accepted in Canada should pursue their convictions only through legal and democratic means.

## Introduction

Ms. Y is 32 years old and has advanced gastric cancer that has resulted in constant severe pain and poorly controlled vomiting. Despite steady increases in her morphine dose, her pain has worsened greatly over the last 2 days. Death is imminent, but the patient pleads incessantly with the hospital staff to "put her out of her misery."

Mr. Z is a 39-year-old injection drug user with a history of alcoholism and depression. He presents at an emergency department, insisting that he no longer wishes to live. He repeatedly requests euthanasia on the grounds that he is no longer able to bear his suffering (although he is not in any physical pain). A psychiatrist rules out clinical depression.

### What are euthanasia and assisted suicide?

A special Senate committee appointed to inform the national debate on euthanasia and assisted suicide defined euthanasia as "a deliberate act undertaken by one person with the intention of ending the life of another person to relieve that person's suffering where the act is the cause of death."[1] Euthanasia may be "voluntary," "involuntary" or "nonvoluntary," depending on (a) the competence of the recipient, (b) whether or not the act is consistent with his or her wishes (if these are known) and (c) whether or not the recipient is aware that euthanasia is to be performed.

Assisted suicide was defined by the Senate committee as "the act of intentionally killing oneself with the assistance of another who deliberately provides the knowledge, means, or both."[1] In "physician-assisted suicide" a physician provides the assistance.

### Why are euthanasia and assisted suicide important?

There is increasing pressure to resolve the question of whether physicians and other health care professionals should in certain circumstances participate in intentionally bringing about the death of a patient and whether these practices should be accepted by society as a whole. The ethical, legal and public-policy implications of these questions merit careful consideration.

## Ethics

There is considerable disagreement about whether euthanasia and assisted suicide are ethically distinct from decisions to forgo life-sustaining treatments.[2–10] At the heart of the debate is the ethical significance given to the intentions of those performing these acts.[11,12] Supporters of euthanasia and assisted suicide reject the argument that there is an ethical distinction between these acts and acts of forgoing life-sustaining treatment. They claim,

instead, that euthanasia and assisted suicide are consistent with the right of patients to make autonomous choices about the time and manner of their own death.[2,13]

Opponents of euthanasia and assisted suicide claim that death is a predictable consequence of the morally justified withdrawal of life-sustaining treatments only in cases where there is a fatal underlying condition, and that it is the condition, not the action of withdrawing treatment, that causes death.[14] A physician who performs euthanasia or assists in a suicide, on the other hand, has the death of the patient as his or her primary objective.

Although opponents of euthanasia and assisted suicide recognize the importance of self-determination, they argue that individual autonomy has limits and that the right to self-determination should not be given ultimate standing in social policy regarding euthanasia and assisted suicide.[15]

Supporters of euthanasia and assisted suicide believe that these acts benefit terminally ill patients by relieving their suffering,[16] while opponents argue that the compassionate grounds for endorsing these acts cannot ensure that euthanasia will be limited to people who request it voluntarily.[17] Opponents of euthanasia are also concerned that the acceptance of euthanasia may contribute to an increasingly casual attitude toward private killing in society.[18]

Most commentators make no formal ethical distinction between euthanasia and assisted suicide, since in both cases the person performing the euthanasia or assisting the suicide deliberately facilitates the patient's death. Concerns have been expressed, however, about the risk of error, coercion or abuse that could arise if physicians become the final agents in voluntary euthanasia.[19] There is also disagreement about whether euthanasia and assisted suicide should rightly be considered "medical" procedures.[20,21]

## Law

### Canadian legislation

The Criminal Code of Canada prohibits euthanasia under its homicide provisions, particularly those regarding murder, and makes counselling a person to commit suicide and aiding a suicide punishable offences. The consent of the person whose death is intended does not alter the criminal nature of these acts.[22]

### Canadian case law

In 1993 the Supreme Court of Canada dismissed (by a 5–4 margin) an application by Sue Rodriguez, a 42-year-old woman with amyotrophic lateral sclerosis, for a declaration that the Criminal Code prohibition against aiding or abetting suicide is unconstitutional. Rodriguez claimed that Section 241(b) of the Code violated her rights under the Charter of Rights and Freedoms to liberty and security of the person, to freedom from cruel and unusual treatment and to freedom from discrimination on grounds of disability, since the option of attempting suicide is legally available to nondisabled people.[6]

Despite the reaffirmation by the court in the Rodriguez case that assisting in the suicide of another per-son is appropriately viewed as a criminal activity, there has been a clear trend toward leniency at laying charges and at sentencing for those individuals, some of them physicians, convicted of such offences.[23,24] At the time of writing, a Toronto doctor had been charged with 2 separate counts of aiding a suicide. He is the first Canadian physician to be charged under Section 241(b) of the Criminal Code. The outcome of his trial, which is expected to be completed by the end of 1997, will likely be of great importance in shaping Canadian law on the matter.

### Other jurisdictions

On Sept. 22, 1996, a cancer patient in Australia's Northern Territory became the first person in the world to receive assistance from a physician to commit suicide under specific legislation.[25] In The Netherlands, a series of judicial decisions has made euthanasia permissible under certain guidelines since the 1960s, despite the fact that it is still officially a criminal offence. Several legislative initiatives in the US have either been narrowly defeated[26] or have met with a constitutional challenge.[27]

Recently, 2 federal courts of appeal in the US independently ruled that there is a constitutionally protected right to choose the time and manner of one's death, and that this right includes seeking assistance in committing suicide.[4,5] In the fall of 1996 the US Supreme Court began to hear arguments in appeals of both cases. The court's decision is expected by the summer of 1997.

### Policy

In 1993, Sawyer, Williams and Lowy identified 4 public- policy options available to Canadian physicians with regard to euthanasia and assisted suicide: (a) oppose any change in the legal prohibition, (b) support a modification of the law to permit euthanasia or assisted suicide or both under certain circumstances only, (c) support decriminalization on the assumption that there will be legislation to prevent abuse and (d) maintain neutrality.[28] Despite differences of opinion within its membership, the CMA continues to uphold the position that members should not participate in euthanasia and assisted suicide.[29] This policy is consistent with the policies of medical associations throughout the world.[30]

### Empirical studies

### Perspectives of patients and the public

Requests for euthanasia and assisted suicide do not arise exclusively out of a desire to avoid pain and suffering. Clinical depression,[31] a desire to maintain personal control,[32] fear of being dependent on others[33] and concern about being a burden to loved ones[34] have all been reported as reasons underlying requests for euthanasia and assisted suicide.

In Canada, more than 75% of the general public support voluntary euthanasia and assisted suicide in the case of patients who are unlikely to recover from their illness.[35] But roughly equal numbers oppose these practices for patients with reversible conditions (78% opposed),

elderly disabled people who feel they are a burden to others (75% opposed), and elderly people with only minor physical ailments (83% opposed).[36]

### Physicians' perspectives and practices

Results of a survey by Kinsella and Verhoef indicate that 24% of Canadian physicians would be willing to practice euthanasia and 23% would be willing to assist in a suicide if these acts were legal.[37] These findings are similar to the results of surveys conducted in the UK[38] and in Australia's Northern Territory.[39] Surveys of physicians in the Australian state of Victoria,[40] as well as recent surveys in Oregon,[41] Washington[30] and Michigan[42] indicated that a majority of physicians in these jurisdictions supported euthanasia and assisted suicide in principle and favored their decriminalization. Some studies have documented physician participation in euthanasia and assisted suicide.[30,38,43] Physicians in certain specialties (such as palliative care) appear to be less willing to participate in euthanasia and assisted suicide than physicians in other specialties.[27,34,37]

## How should I approach euthanasia and assisted suicide in practice?

Euthanasia and assisted suicide violate the Criminal Code of Canada and are punishable by life imprisonment and 14 years in prison, respectively. Physicians who believe that euthanasia and assisted suicide should be legally accepted in Canada should pursue these convictions through the various legal and democratic means at their disposal, i.e., the courts and the legislature. In approaching these issues in a clinical setting it is important to differentiate between:
(a) respecting competent decisions to forgo treatment, such as discontinuing mechanical ventilation at the request of a patient who is unable to breathe independently, which physicians may legally do; (b) providing appropriate palliative measures, such as properly titrated pain control, which physicians are obliged to do; and (c) acceding to requests for euthanasia and assisted suicide, both of which are illegal.

### The cases

The case of Ms. Y involves a competent, terminally ill patient who is imminently dying and in intractable pain. The case of Mr. Z involves an apparently competent patient who is not dying but is experiencing extreme mental suffering.

In both cases the physician is confronted with a request to participate in euthanasia or assisted suicide. The physician should explore the specific reasons behind the request and provide whatever treatment, counselling or comfort measures that may be necessary. For example, for Ms. Y, it may be necessary to seek the advice of a pain specialist about alternative approaches to pain management and palliation. The case of Mr. Z is in many ways more difficult, since depression has been ruled out as a contributing factor in the request. The physician must attempt to investigate and ameliorate any other psychosocial problems that are affecting the patient.

Providing euthanasia and assisted suicide in either case could result in conviction and imprisonment. However, increasing the morphine dosage for Ms. Y as necessary to relieve her pain is lawful, even though it may eventually prove toxic and precipitate death.

## Ethical dilemmas that arise in the care of pregnant women: rethinking "maternal–fetal conflicts"


### Abstract

When a pregnant woman makes a decision or acts in a manner that may be detrimental to the health and well-being of her fetus, her physician may be faced with an ethical dilemma. Is the physician's primary duty to respect the woman's autonomy, or to promote behavior that may be in the best interest of the fetus? The controversial concept of "fetal rights" or the "fetus as a patient" contributes to the notion that the pregnant woman and her fetus are potential adversaries. However, Canadian law has upheld women's right to life, liberty and security of the person and has not recognized fetal rights. If a woman is competent and refuses medical advice, her decision must be respected even if the physician believes that her fetus will suffer as a result. Coercion of the woman is not permissible no matter what appears to be in the best interest of the fetus.


### Introduction

Ms. A is 19 years old and is 25 weeks pregnant. During a prenatal office visit she reveals that her partner is bisexual and may have been exposed to HIV. Her physician advises her to have an HIV test, explaining that if she is seropositive treatment is available that may slow the disease process. Moreover, treatment may reduce the risk of HIV transmission to the fetus. In spite of this information, Ms. A refuses HIV testing.

Ms. B is 24 years old and has been in labor for 18 hours. The cervical dilatation has not progressed past 3 cm. The fetal heart rate tracing has been worrisome but is now seriously abnormal, showing a profound bradycardia of 65 beats per minute. This bradycardia does not resolve with conservative measures. Repeat pelvic examination reveals no prolapsed cord and confirms a vertex presentation at 3 cm dilatation. The obstetrician explains to Ms. B that cesarean section will be necessary in view of the fetal distress. Ms. B absolutely refuses, saying "No surgery."

### What are maternal–fetal dilemmas?

When a physician believes that he or she has a moral obligation to pursue 2 conflicting courses of action, he or she faces a moral dilemma.[1] In the care of pregnant women, moral dilemmas can arise when the physician believes that her obligation to respect a patient's decision conflicts with her obligation to protect the fetus from harm. This conflict can arise in at least 3 separate realms, that is, with respect to the woman's personal health care choices, lifestyle and behaviors, and occupational situation. In practice and in the literature, these unfortunate situations are often described as "maternal–fetal conflicts."[2–4]

The use of this term is problematic for several reasons. First, it situates the conflict between the pregnant woman and the fetus, whereas the conflict is really between the pregnant woman and

others who believe that they know best how to protect the fetus.[5] These others may be seen to act from a sense of professional duty or as agents of the state [on behalf of society at large] and may include third parties such as child welfare agencies, physicians and other health care providers.[3,4,6] Second, the term perpetuates the underlying but unfounded assumption that the problem involves the opposition of maternal rights against fetal rights. At most, there is a conflict between the woman's autonomy and the best interest of the fetus. Some caregivers are committed to respecting the pregnant woman's wishes; others deem that state intervention to protect the fetus is both necessary and appropriate in some circumstances. Finally, the term "maternal–fetal conflict" is factually incorrect. The term "maternal" suggests the existence of parental obligation toward the fetus, whereas the woman is *yet to become* a mother to the fetus she is carrying. This is a significant distinction. Although the term "maternal–fetal conflicts" has gained currency, we advocate the use of the more descriptive phrase, "ethical dilemmas that arise in the care of pregnant women."

## Why are ethical dilemmas that arise in the care of pregnant women important?

### Ethics

The principle of reproductive freedom stipulates that people have the right to make their own reproductive choices and that the state has an obligation to foster conditions under which this can occur.[7] For some, this principle is morally objectionable because it grants women the right to make decisions concerning the termination of unwanted pregnancies. In their view, whatever rights the pregnant woman may or may not have do not override the fetus' right to life. The problem with this position is that typically it rests on the highly contested premise that the fetus, like the pregnant woman, is a person -- someone whose interests and rights must be respected.

Others do not reject the principle of reproductive freedom but at the same time advocate what they believe to be legitimate restrictions on this principle as it applies to women. They maintain that although the fetus may not have the rights of a person, once the woman has decided "of her own free will" to continue the pregnancy she has obligations to the fetus. Moreover, the state may intervene to limit or preclude actions that would irreversibly harm the fetus.[8,9] Again, this position is problematic. It suggests an opposition between the interests of the woman and those of the fetus, and overlooks the important fact that these interests are inextricably linked. The few women who do risk harming their fetuses typically do not actively seek to cause such harm.

All things being equal, women who bring their pregnancy to term do not want damaged babies. But alas, sometimes a woman's choices are made in ignorance, or are informed by deeply held religious or personal beliefs that preclude certain decisions, or result from strong social and psychological pressures. Any one of these factors can prevent a woman from acting in the best interest of her fetus. Consider, for example, a woman who fears physical and psychological abuse or abandonment by her partner and therefore refuses voluntary HIV testing that might indicate the need for immediate drug therapy to prevent vertical transmission. Were her circumstances different, she would prefer not to have her child born to possibly suffer and die from HIV infection.[10] It should also be noted that continuing a pregnancy does not always involve a deliberate, active choice on the part of the woman. Similarly, many behaviors that

may ultimately harm a fetus cannot properly be described as choices, as in the case of addictions.

Recognizing such limitations, some may still argue that state intervention -- including forced screening, forced incarceration to prevent continued substance abuse, and forced obstetrical interventions -- is morally justified. However, when the issue is considered in its broader social and political context it becomes clear that such interventions are indefensible. First, such coercion is far in excess of any nonvoluntary intervention that would be tolerated to save nonfetal lives. For example, parents are not coerced to become organ donors even when a failure to do so would likely result in the death of their child. We may consider a parent's refusal to make such a donation to be morally reprehensible, but it is beyond the realm of state authority. To coerce a pregnant woman to accept efforts to promote fetal well-being is an unacceptable infringement of her personal autonomy.[11,12]

Second, the harm to women that such coercion represents often occurs without any countervailing benefit to the fetus. For example, there are reports of healthy infants delivered after the woman refused consent for cesarean section that was deemed necessary.[11] Third, state intervention is likely to discourage women whose fetuses may be most at risk from seeking appropriate care.[11,12] It is also likely to undermine the trust between pregnant women and their health care providers that is necessary to foster the education that would promote the birth of healthier babies.

Finally, state intervention to promote fetal well-being is hypocritical given the inconsistency between aggressive efforts made to rescue a few fetuses from a few women in unfortunate situations and the widespread tolerance for unacceptable and sometimes dangerous living conditions in which many children find themselves.

**Law**

Canadian law addresses 2 issues relevant to this discussion: it confirms the competent woman's right to refuse treatment and the absence of fetal rights. First, informed consent is a legal necessity in medical practice.[13] Physicians who treat a competent patient without his or her consent put themselves at risk of both criminal and civil liability.[14,15] As well, coercive treatment of a woman by the state contravenes the Canadian Charter of Rights and Freedoms, which recognizes that women and men have equal rights to life, liberty and security of the person.[16]

Second, in common law the fetus does not have legal rights until it is born alive and with complete delivery from the body of the pregnant woman.[17–19] For this reason child protection legislation [which, under certain circumstances, authorizes state intervention] does not apply to the fetus.[20]

A recent decision of the Manitoba Court of Appeal confirms this position.[21] Although the decision of the lower court suggested that there was legal authority to order a pregnant woman to undergo, without consent, counselling and hospital admission to manage a drug addiction, the Court of Appeal confirmed that there was no legal basis on which to do so. This decision

confirmed that the fetus is not protected before birth under Canadian law and that the courts have no legal grounds on which to order a competent pregnant woman to undergo a medical intervention that she does not want. An appeal of this case will be heard by the Supreme Court of Canada.

**Policy**

The CMA Code of Ethics stipulates that a physician "must respect the right of a competent patient to accept or reject any medical care recommended."[22] Consistent with this position is the recommendation of the Royal College of Physicians and Surgeons of Canada that when a physician's view of the best interest of the fetus conflicts with the view of the pregnant woman, the role of the physician is to provide counselling and persuasion, but not coercion.[23]

This view is discussed more fully in the Final Report of the Royal Commission on New Reproductive Technologies,[24] which recommended that:

- medical treatment never be imposed upon a pregnant woman against her wishes,
- criminal law, or any other law, never be used to confine or imprison a pregnant woman in the interest of her fetus,
- the conduct of a pregnant woman in relation to her fetus not be criminalized,
- child welfare or other legislation never be used to control a woman's behavior during pregnancy, and
- civil liability never be imposed upon a woman for harm done to her fetus during pregnancy.

**Empirical studies**

One of the justifications for state intervention in pregnancy is the belief that it benefits the fetus. However, reports of good fetal outcomes despite a woman's refusal of cesarean section call this assumption into question.[11,25,26] Unfortunately, there is no standardized system for documenting and assessing cases in which a pregnant woman refuses medical advice.

A review of the few cases that have reached the courts in Canada shows unequivocally that state intervention is disproportionately oppressive of poor women, aboriginal women and women who are members of other racial and ethnic minorities.[27] This finding is cause for concern.

Moreover, the almost exclusive focus on the impact of pregnant women's behaviors and choices on the health and well-being of the fetus reflects an unacceptable gender bias. There is ample evidence to show that paternal drug and alcohol abuse, excessive caffeine and nicotine use, spousal abuse and certain paternal occupations are also potentially hazardous to the fetus.[28–30]

Finally, when attention is directed only toward the pregnant woman's behaviors and choices, the fact that "malnutrition, violence, chaotic lives, serious maternal health problems and lack of

medical care"[31] have a significant impact on the health and well-being of the fetus is often overlooked.

**How should I approach ethical dilemmas that arise in the care of pregnant women?**
Although Canadian law does not recognize fetal rights, fetal interests are taken into consideration by physicians and their pregnant patients. In fact, with the development of detailed ultrasound imaging, excellent perinatal technology and the ability to improve outcomes for very small infants, it is hard for many physicians not to envision the fetus as a patient.[2,32] Thus, some physicians see themselves as having responsibility for 2 "patients" in 1 body. It is extraordinarily difficult for a physician to stand by while a fetus dies or becomes irreparably harmed when an intervention might prevent this result. Nonetheless, it is still inappropriate either to coerce a patient to undergo an intervention or to abandon her.

Difficult as it may be, the physician must respect the competent woman's right to make decisions for herself and her fetus. Moreover, care must be taken not to question the competence of the woman merely because she does not concur with one's recommendations. The most common reason for rejecting medical advice is not incompetence but fear of the unknown. Other possible reasons are denial, past experience, a bias toward the present and near future, and a lack of trust in the medical profession.[33]

Communication, understanding and respect for women are essential in the management of these difficult situations. However, no matter how skilled a communicator the physician might be, a woman may for reasons of her own not alter her decision or behavior. The physician's communication skills may be significantly tested in such cases [especially when a decision is needed urgently], and it may be difficult to develop the trust that is integral to the physician–patient relationship.

As in other challenging medical situations, consultation with a colleague can be extremely helpful.

**The cases**
Because the treatment of HIV-seropositive pregnant women is believed to benefit the fetus, there is ongoing debate about mandatory HIV testing for pregnant women.[34] However, to respect a pregnant woman's autonomy this intervention may not occur without her explicit consent. Issues of possible prejudice or bias with regard to employment, insurance, housing and so on may factor significantly in decisions about HIV testing. From a practical perspective, it is worth emphasizing that testing alone is not an effective intervention that benefits the fetus. If a woman is found to be HIV seropositive, she has the right to refuse treatment even if such treatment is potentially beneficial to the fetus. Therefore, despite the increased risk that Ms. A may be HIV seropositive, the physician must respect her refusal of HIV testing.

Further discussion clarifies that Ms. B is terrified of general anesthesia because her mother died from anesthesia complications. Moreover, Ms. B has a strong distrust of physicians and believes that too many cesarean sections are done. When it is explained that the cesarean can be done with spinal anesthesia, and in view of the risks of the ongoing bradycardia, Ms. B

agrees to the surgery. However, if the patient had continued to refuse the surgery, the physician would have been obliged to respect her decision despite the serious risks to the fetus.

## Resource allocation


### Abstract

Questions of resource allocation can pose practical and ethical dilemmas for clinicians. In the Aristotelian conception of distributive justice, the unequal allocation of a scarce resource may be justified by morally relevant factors such as need or likelihood of benefit. Even using these criteria, it can be difficult to reconcile completing claims to determine which patients should be given priority. To what extent the physician's fiduciary duty toward a patient should supersede the interests of other patients and society as a whole is also a matter of controversy. Although the courts have been reluctant to become involved in allocation decisions in health care, they expect physicians to show allegiance to their patients regardless of budgetary concerns. The allocation of resources on the basis of clinically irrelevant factors such as religion or sexual orientation is prohibited. Clear, fair and publicly acceptable institutional and professional policies can help to ensure that resource allocation decisions are transparent and defensible.


### Introduction

Mr. C is a 21-year-old computer programmer with cystic fibrosis. Chronic rejection and poorly controlled fungal infections are destroying the lungs he received 15 months ago. He has intermittently required positive-pressure ventilation to maintain adequate oxygenation during flare-ups of infection or rejection. Mr. C has been listed as a candidate for a second transplantation. However, given the presence of infection and the risks associated with repeat transplantation, his predicted chance of survival is 65% at 1 month and 38% at 24 months.[1]

Mrs. D is a 42-year-old schoolteacher. She has been listed as a candidate for double lung transplantation because of rapidly progressing pulmonary hypertension associated with hemoptysis and hypoxemia. She is unable to manage at home because of decompensated right heart failure unresponsive to maximal therapy. As a first-time lung transplant candidate who is free of infection, Mrs. D has a predicted chance of survival of 82% at 1 month and 62% at 2 years.[1]

The surgeon has 1 matching donor organ available for these 2 patients. He knows that the best outcome can be achieved by transplanting both lungs of the donor into the same patient.[2]

When 63-year-old Mr. E is brought to the emergency department with severe but potentially reversible brain injury after a motor vehicle accident, the attending physician considers going through the charts of each patient in the intensive care unit (ICU) in the hope of finding someone whose need for intensive care is less than that of Mr. E. She also considers sending Mr. E to the floor, but knows that this will overtax the capabilities of the floor staff, who are

not prepared to manage the patient's elevated intracranial pressure and seizures. Because of recent hospital closures in the region, no other facility is available to share responsibility for the care of patients with neurosurgical problems of this magnitude.

**What is resource allocation?**

Resource allocation is the distribution of goods and services to programs and people. In the context of health care, macroallocations of resources are made by governments at the national, provincial and municipal level. Mesoallocations are made at the level of institutions; for example, hospitals allocate their resources to programs such as cancer treatment, cardiology and dialysis. Microallocations are made at the level of the individual patient. Although these 3 levels are interrelated, in this article we focus on resource allocation from the perspective of the practicing physician.

Commodity scarcity, illustrated by the lung-transplant case, is a shortage of a finite resource (such as an organ) because of natural limits to the availability of that resource. Fiscal scarcity, illustrated by the intensive care case, is a shortage of funds.[3]

**Why is resource allocation important?**

Rising public and professional expectations, an expanding pool of treatable patients and costly new technology must be balanced against tightly monitored health care budgets, competing government priorities and provincial deficits. Ethics, law, policy and empirical studies provide insights that can help clinicians as they try to distribute health care resources fairly.

**Ethics**

The ethics of resource allocation may be considered in relation to the concept of justice and the physician's fiduciary duty toward the patient.

According to Aristotle's principle of distributive justice, 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.[4] Characteristics such as sex, sexual orientation, religion, level of education or age alone are morally irrelevant criteria for resource allocation. Because there is no overarching theory of justice to balance competing claims between morally relevant criteria such as need and benefit, fair, open and publicly defensible resource allocation procedures are critical.

The lack of a comprehensive theory of justice gives rise to unresolved issues in rationing; these have been categorized by Daniels as follows.[5]

- The fair chances versus best outcomes problem. To what degree should producing the best outcome be favored over giving every patient an opportunity to compete for limited resources?
- The priorities problem. How much priority should we give to treating the sickest or most disabled patients?
- The aggregation problem. When should we allow an aggregation of modest benefits to larger numbers of people to outweigh more significant benefits to fewer people?

- The democracy problem. When must we rely on a fair democratic process as the only way to determine what constitutes a fair rationing outcome?[5]

These questions help to frame discussions of resource allocation issues and the development of policies and practices that balance the obligations of physicians as citizens in a just society with their obligations to individual patients.

The power imbalance that exists between physician and patient creates a fiduciary duty on the physician's part 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. For instance, Levinsky has argued that "physicians are required to do everything that they believe may benefit each patient without regard to costs or other societal considerations."[6] By contrast, Morreim 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, of society as a whole, and sometimes even of the physician himself."[7]

**Law**

The Canadian Charter of Rights and Freedoms prohibits discrimination on various grounds, including physical or mental disability, but it applies only to governmental agencies, not to physicians or hospitals[8] unless they are under the day-to-day control of ministries of health or other branches of government.[9]

Human rights codes in several provinces prohibit discrimination on the basis of race, ethnicity, place of origin, religion, age, sex, sexual orientation and physical or mental disability. Evidence that resources were allocated purely on such grounds could lead to an inquiry and legal proceedings by a provincial human rights commission. However, if such factors were relevant to a medical prognosis, it is not clear how a human rights commission could challenge a physician's clinical assessment of a patient's eligibility for a particular treatment. Evidence might be needed of a systematic policy of discrimination or bias against a particular group on the part of the practitioner or institution.[10]

Because courts have been extremely reluctant to become involved in how physicians, hospitals and health authorities use their resources, the legal review of individual decisions involving resource allocation is improbable.[11] As a British judge has observed, "Difficult and agonizing judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients. That is not a judgment which the court can make."[12]

Nevertheless, the trial judge in a case heard in BC criticized physicians for offering the explanation that they felt too constrained by the provincial medical insurance plan and their provincial medical association's standards to order a diagnostic CT scan. Although a finding of negligence was made on other grounds, the judge noted that while physicians may consider the financial impact of their decisions, financial considerations cannot be decisive. The physician's first duty is to the patient.[13]

It is understood in law that although there is no liability for making a decision that proves to be wrong,[14] there may be liability for making a decision *wrongly*. A decision is made wrongly if demands for economy distort the physician's judgment with respect to the care that is owed to the patient. An error in clinical judgment is not actionable, because the risk of being wrong is inherent in every exercise of judgment. However, to take decisive account of secondary concerns and subordinate the primary concern of care -- the patient's well-being -- to a budgetary issue is the wrong way for a physician to make a treatment decision.

**Policy**

Clear, fair and widely accepted institutional or professional policies can provide guidance for physicians who are faced with difficult resource allocation decisions. Policies developed for the allocation of organs have reduced conflict between teams and helped prioritize recipients within organ transplantation programs, using generally accepted and publicly reviewed principles and guidelines.[15]

In Oregon, a priority list of treatments is being developed by citizens' committees with input from physicians. This evolving experiment in public policy ranks health care services on the basis of effectiveness and perceived value to the community. Public funds are assigned by the government to make services "above the funding line" available to citizens "below the poverty line".[16] Public funds assigned by the government to pay for health care are spent on treatments according to their priority on the list. Through multiple iterations and public debate, this experiment is producing a useful model for engaging stakeholders from government, the medical profession and the public in the process of health policy development.[17,18]

In Canada, the CMA has provided a framework for decision-making on core and comprehensive health care services that incorporates 3 major dimensions: quality, economics and ethics.[19] As well, Deber and colleagues have proposed a "four-screen" model based on effectiveness, appropriateness, informed choice and public provision.[20] Finally, the CMA' s Code of Ethics states that physicians should "recognize [their] responsibility to promote fair access to health care resources" and should "use health care resources prudently."[21]

**Empirical studies**

Given the importance of resource allocation decisions in health care today, there is a surprising lack of empirical studies on this topic. In contrast to the hundreds of published studies on advance directives,[22] for example, fewer than 2 dozen empirical studies on resource allocation (excluding cost-effectiveness analyses of various diagnostic tests and treatments) came to light in our literature search. In this section we review some of these studies with reference to the primary question they address.

*Is resource allocation occurring now?* In a study of dialysis referrals, Mendelssohn and associates found that 67% of Ontario physicians believed rationing of dialysis was occurring at the time of the survey and 91% believed that such rationing would occur in the future.[23]

*How do health care providers make resource allocation decisions?* This question has been addressed by survey methods in the context of dialysis,[23] transplantation,[24–26] rural medicine,[27] and critical care.[28] For instance, a survey by the Society of Critical Care

Medicine found that critical care physicians considered quality of life as viewed by the patient, probability of survival, the reversibility of the acute disorder and the nature of any chronic disorder as important factors in deciding which patients to admit to the intensive care unit.[28]

*Do people consider age a relevant variable in health care resource allocation?* In a survey of public opinion in the US, Zweibel and colleagues[29] found that most people accept the withholding of life-prolonging medical care from some critically ill older patients, but few would categorically withhold such care on the basis of age alone.

*How do decision-makers balance concerns of efficiency and equity?* Ubel and collaborators[30] surveyed prospective jurors, medical ethicists and experts in medical decision-making to explore the trade-off between cost-effectiveness and equity in the setting of budget constraints. Many respondents said they would choose a less cost-effective test for the entire population over a more cost-effective test for half the population. Similarly, in a survey of public opinion in Australia, Nord and associates[31] found that a policy of maximizing cost-effectiveness received very limited support when the consequence was a loss of equity and access to services for elderly people and for people with limited potential for improving their health. In other words, equity was valued above cost-effectiveness in both of these surveys.

### How should I approach resource allocation in practice?

The clinician's goal is to provide optimal care within the limits imposed by the allocation of resources to health care generally and to the institution, program and specific situation in which an individual patient is treated. The following guidelines may prove helpful in practice.

- Choose interventions known to be beneficial on the basis of evidence of effectiveness.
- Minimize the use of marginally beneficial tests or marginally beneficial interventions.
- Seek the tests or treatments that will accomplish the diagnostic or therapeutic goal for the least cost.
- Advocate for one's own patients but avoid manipulating the system to gain unfair advantage to them.
- Resolve conflicting claims for scarce resources justly, on the basis of morally relevant criteria such as need (e.g., the patient's risk of death or serious harm could be reduced by the treatment) and benefit (e.g., published evidence of effectiveness), using fair and publicly defensible procedures (ideally, incorporating public input).
- Inform patients of the impact of cost constraints on care, but do so in a sensitive way. Blaming administrative or governmental systems during discussions with the patient at the point of treatment should be avoided; it undermines care by reducing confidence and increasing anxiety at a time when the patient is most vulnerable.
- Seek resolution of unacceptable shortages at the level of hospital management (mesoallocation) or government (macroallocation).

## The cases

Mrs. D should receive the double lung. Although her need is approximately equal to that of Mr. C, her ability to benefit is substantially greater. The surgeon knows from sound empirical evidence that repeat lung transplantation has a poor prognosis, particularly when chronic

infection exists.[1] He can minimize recriminations related to the team members' feelings of loyalty toward Mr. C if the transplantation program policy clearly spells out specific and fair procedures to follow when difficult allocation decisions must be made involving similarly deserving patients.

The attending physician should provide appropriate care for Mr. E in the emergency department, as this is the only facility available. She should involve the administrator on call to bring in additional skilled personnel to provide interim care in the emergency department and to help her arrange for the patient's transfer to a facility prepared to care for him. In this way, she clarifies the responsibility of the hospital to resolve the mesoallocation problem at an administrative level. The hospital may in turn address the macroallocation of resources at the provincial or regional level through its representatives to the government. The physician should not attempt to resolve problems of this magnitude on her own and should not compromise the care of Mr. E. She may choose to contribute to the resolution of similar problems in the longer term by making suggestions about system reform to the health ministry or helping with appeals for public support of additional facilities.

## Ethics and genetics in medicine


### Abstract

Information about a patient's inherited risk of disease has important ethical and legal implications in clinical practice. Because genetic information is by nature highly personal yet familial, issues of confidentiality arise. Counselling and informed consent before testing are important in view of the social and psychological risks that accompany testing, the complexity of information surrounding testing, and the fact that effective interventions are often not available. Follow-up counselling is also important to help patients integrate test results into their lives and the lives of their relatives. Genetic counselling should be provided by practitioners who have up-to-date knowledge of the genetics of and the tests available for specific diseases, are aware of the social and psychological risks associated with testing, and are able to provide appropriate clinical follow-up. Some physicians may elect to refer patients for genetic counselling and testing. However, it is inevitable that all physicians will be involved in long-term follow-up both by monitoring for disease and by supporting the integration of genetic information into patients' lives.


Ms. F is a 25-year-old graduate student. She consults a family physician at the university health clinic because she wants to know if she is a genetic carrier of myotonic dystrophy. Although there is no clinical family history, myotonic dystrophy was recently diagnosed in her older sister after she gave birth to a "floppy" baby. The physician takes a blood sample, sends it to a DNA laboratory for testing and tells her to phone in 3 weeks for the results.

Ms. G, a 38-year-old woman with 2 teenage daughters, expressed concern to her family physician about her genetic risk for breast cancer. Breast cancer had been diagnosed in her

mother when she was 40 years old, and premenopausal ovarian cancer had been diagnosed in her aunt. Ms. G reports that her sisters, aged 35 and 40, are healthy and unconcerned. The family physician refers Ms. G to the local hereditary cancer program. Ms. G receives genetic counselling, consents to genetic testing under a research protocol and provides a blood sample. Eighteen months later Ms. G returns to the family physician on an unrelated matter. She is distraught and tells her family physician that she has the *BRCA1* mutation, is at increased risk of dying in the same awful way that her mother had, and that the genetic counselor is pressuring her to tell her sisters.

**What are the ethics of genetics in medicine?**

Molecular genetics is concerned with the process by which the coding sequences of DNA are transcribed into proteins that control cell reproduction, specialization, maintenance and responses. Inherited or acquired biologic factors that result in an error in this molecular information processing can contribute to the development of a disease. Medical genetics involves the application of genetic knowledge and technology to specific clinical and epidemiologic concerns. Although many common diseases are suspected of having a genetic component, few are purely genetic in the sense that the genetic anomaly is adequate to give rise to the disease. In most cases, genetic risk factors must be augmented by other genetic or environmental factors for the disease to be expressed. Moreover, the detection of a genetic anomaly associated with a disorder such as Down's syndrome does not help us to predict the severity with which the syndrome will be expressed.

Predictive testing does exist for a number of monogenic disorders, such as Huntington's disease.[1,2] Genetic testing can be used to confirm a clinical diagnosis, to detect a genetic predisposition to a disease so that preventive measures can be taken or to help a patient prepare for the future, or to give parents the option of terminating a pregnancy or beginning treatment as early as possible.[3] Genetic testing conducted during research contributes to our understanding of the mechanisms of disease and may eventually allow us to identify which subtypes of a syndrome respond well to treatment and which do not. However, the clinical use of genetic testing, which has become common because of its widespread use in research, has been premature. The social and psychosocial implications of genetic information are not well understood, and the development of useful clinical responses to the results of testing has not kept pace with the development of genetic tests.

Certain ethical and legal responsibilities accompany the flood of genetic knowledge into the current practice of medicine. This is because of 3 general characteristics of genetic information: the implications of genetic information are simultaneously individual and familial; genetic information is often relevant to future disease; and genetic testing often identifies disorders for which there are no effective treatments or preventive measures.

## Why are the ethics of genetics important in medicine?

### Ethics

Although there is no single ethical issue that unifies the field of genetics, informed consent, confidentiality and the potential for social harm and psychological distress are issues that physicians involved with testing should understand. The case examples illustrate the 2 issues, consent to genetic counselling and confidentiality, that family physicians are most likely to be confronted with when managing patients in whom family history or genetic testing may provide valuable genetic information.

Informed consent, which must be obtained before genetic tests are conducted, requires that patients participate in health care decisions. Obtaining informed consent to genetic testing is particularly challenging in view of the complexity of genetic information, the controversial nature of clinical options such as abortion or prophylactic surgery of unknown efficacy, and the social and psychological implications of testing.[4,5] Positive genetic test results are rarely accompanied by the prospect of either treatment or cure. In the absence of effective treatment, the potential for psychological harm and social discrimination must be considered. Patients must evaluate whether the benefit of testing is worth the risk. When genetic testing is part of research, the purpose of the research should be made clear to the patient and uncertainties that might arise as a result of testing discussed.[6]

Patients have the right to control the use of all medical information about themselves, including genetic information.[7] The predictive or risk-assessing nature of genetic information makes it valuable to health care planners, insurers, and people evaluating long-term concerns such as education, career choices, and risk avoidance and health promotion.[3] The possibility of insurance discrimination has made the confidentiality of genetic information even more important.[8,9] Physicians should ensure that patients understand that after genetic testing their ability to qualify for insurance may be affected. Even though including in clinical records the results of genetic testing conducted in the course of research is not always appropriate,[10] the legal definition of "health care record" includes *all* written information about a patient. Separate records provide little protection to the patient and may compromise care if the genetic information is such that it would affect treatment in the future or be of interest to a family member. Departments of medical genetics do maintain familial records that link the genetic records of individual patients to assist with the clinical services they provide. Nevertheless, information from these records is typically shared with family members only with the consent of the person whose test results are being disclosed. The familial nature of genetic information can create a conflict for the physician, who has a duty to maintain confidentiality but may feel a duty to warn family members of possible risk. Ultimately, the issues of duty to warn and access to health care records will probably be decided by legislation, whereas consent and access to genetic testing will be evaluated on the basis of social and psychological risk.

## Law

Although a ban on germ-line genetic therapy and on prenatal screening for sex selection was proposed as part of the Human Reproductive and Genetic Technologies Act (Bill C-47),[11] currently there is no specific legislation relating to the use of genetic information in Canada. There are 3 main legal issues that apply to clinical genetics: informed consent to testing; standard of care, including genetic counselling for adults and pregnant women wanting to undergo testing; and the duty to warn family members who may be at risk.

There are other legal and ethical issues that are beyond the clinical focus of this article. One is whether patent laws that apply to genetic research serve the public interest.[12] A second is whether legislation should protect people from the use of genetic tests as a basis for discrimination by employers and insurers.

Explicit informed consent to a genetic test is required because genetic testing carries considerable risk of social harm in the form of discrimination. A patient might reasonably consider that the possibility of discrimination would outweigh the benefits of the test, particularly if no effective treatment or preventive measures are available.

There is no standard of care for clinical genetic practice, and the test and counselling programs that are offered vary among provinces. However, current case law indicates that physicians have a legal obligation to inform patients of the availability of prenatal testing.[13–15] Generally, geneticists suggest that obstetricians offer prenatal tests when the risk of a serious genetic condition outweighs the risk of spontaneous miscarriage caused by amniocentesis or chorionic villae sampling. Much genetic testing is conducted as research, and aspects of a study design, such as the use of cloning or the objective of gene therapy, may be relevant to physicians or patients. Ethical concerns specific to genetic research are beyond the scope of this article and are discussed elsewhere.[6,10,16,17]

The duty to warn family members about a genetic condition is based on the premise that the warning is necessary to avert serious harm. As discussed in an earlier article in this series,[7] any breach of confidentiality must be based on a realistic assessment of whether the disclosure will effectively prevent serious harm. This breach of confidentiality is rarely justified, except in cases where prevention or treatment is possible, such as for familial adenomatous polyposis.[18–20] A physician contemplating warning a family member about a genetic risk should be able to answer "yes" to the following questions:

- Is the family member at a high risk of serious harm?
- Does the breach of confidentiality actually make it possible to prevent or minimize the harm?
- Is the breach of confidentiality necessary to prevent or minimize the harm (i.e., has the patient refused to disclose the information or to give consent for its disclosure).

### Policy

Policy guidelines and recommendations are often established for specific diseases with genetic components. The most common theme of such guidelines is the requirement for pre- and post-test genetic counselling. The importance of having a competent professional provide the counselling has been noted, but there are not enough specifically trained genetic counselors or clinical geneticists to handle the anticipated caseload as genetic testing becomes more common.[21,22] There is general agreement that health care professionals who provide genetic counselling must be well-informed about the nature of the condition and the social and psychological implications of genetic testing, and must be able to interpret the test results and assess specific familial genetic risks.[23–27]

### Empirical studies

Much of the empirical work in genetics and ethics has related to studies of knowledge of genetics, attitudes toward testing, and the psychological effects of available genetic tests. These studies have shown that among Canadian health care professionals, understanding of genetics is poor[21] and there is wide practice variation with respect to genetic testing.[22] Most research into specific diseases suggests that when it is accompanied by adequate counselling, genetic testing is safe and beneficial, even when effective treatments or preventive measures are not available. For example, studies of predictive testing for Huntington's disease found that the psychological well-being of patients improved after testing, and few of the suicidal and depressive episodes that were anticipated actually occurred.[27–29] Despite an emphasis on a nondirective presentation of all options in genetic counselling, studies have found that the subtle influence of counselors' values may affect patients' choices.[30–33] Psychologists and members of families at risk have pushed for research that is more process- and family-oriented,[34,35] and new studies have tried to determine the effect genetic knowledge has on self-concept and family relationships. Some studies even suggest that the most significant and ethically relevant effects of genetic testing may be on the relationship between the health care provider and the patient and among family members.[36–39]

## How should I approach ethics and genetics in the practice of medicine?

Media coverage and the very significant investment being made in genetic research will likely increase the number of patients who want to discuss genetic risk and testing with their family physicians. It is not appropriate to simply order genetic tests and then deal with the results and implications if the test is "positive." Consent and confidentiality require a thorough discussion and realistic planning before the test is conducted.

Genetic counselling has been developed to manage the delivery of complex information and the moral controversies surrounding such issues as abortion and lifestyle changes. It also meets the ethical requirement of informed consent and provides support for patients facing testing. Counselling involves a detailed disclosure and supportive discussion designed to help patients

understand these issues as well as those related to genetic research and duties to family members (e.g., banking of tissue samples for future DNA testing, the social risks and obligations of patients to family members that may affect confidentiality).[17,40,41] Counselling should also clearly establish that there is a possibility that paternity might become an issue, but this is not typically included in the information disclosed. Genetic counselling includes following up with patients to ensure that they have been able to integrate test results and their implications into their lives. One of the primary purposes of the testing is to help patients plan for the future. However, genetic counselors and geneticists cannot always anticipate or understand how familial and social influences will affect the way a patient responds to and uses genetic information.[30,36,37,42]

As with all medical information, genetic information should not be disclosed to third parties or family members without the patient's consent. The exceptions are those rare cases where treatment or preventive measures are available and family members are unaware they are at risk.[7,18–20] People buying insurance are frequently required to divulge all risk information and to sign a release form that gives the insurance company access to their health care records, which may include genetic test results (whether clinical or research).[8,9] Concealing genetic test results from an insurance company may nullify a policy, which could negatively affect a person's future health care. When appropriate, the options for DNA banking, including current or future access by family members or researchers should be discussed with the patient.[41] Family physicians and specialists must share the burden of integrating genetic information into the health care system. However, physicians may find that requests related to specific diseases may be too infrequent to justify investing time and resources in learning about them. Physicians who have patients interested in genetic testing will have to evaluate whether to refer those patients to genetic centers or to take on the responsibility of genetic counselling themselves.

## The cases

Ms. F received genetic testing without adequate counselling. In such situations the informed consent may be invalid and the patient may not be adequately prepared for the information the genetic test provides. Results should be delivered in a supportive manner so the patient understands the implications of the test information and can begin to work through the accompanying risks and responsibilities. Delivering the results over the phone is not supportive. In order to counsel a patient, the physician must know and communicate the risk of being a carrier, which can be as high as 50%. The physician should have asked Ms. F why she wanted to know her status to determine whether she understood the purpose of genetic testing and whether genetic testing would meet her needs.

The family physician referred Ms. G to a local hereditary cancer program for counselling and testing. Most genetic counselling programs include a discussion about the need to talk to family members about genetic risks. For genetic testing to be included in a research protocol, counselling would likely be mandated by a research ethics board.[17] The issue that remains is how the family physician can help the woman deal with her test results, including whether and what to tell her sisters. Any breach of confidentiality on the part of the physician must be

justified by the risk of serious harm and the benefits of disclosure. The sisters could be told that they have a 50% chance of having a mutation that would significantly increase the risk of breast or ovarian cancer developing in them before age 65. The physician has no way of knowing how the sisters would react to this information but must assess how useful it would be to them. There is no guaranteed prophylaxis for breast cancer but early detection and treatment may lead to a better outcome. There are social and psychological risks associated with informing and not informing the sisters. At this time, the speculative nature of the benefits of knowing they are at increased risk does not support a legal duty to warn the sisters, although it may be ethically permissible.[22] To respect Ms. G's confidentiality, however, the physician should continue to encourage her to discuss the genetic risks with her sisters.

## Quality end-of-life care

### Abstract

A physician who receives a call from the emergency department to see a patient with heart failure will have a clear framework within which to approach this problem. The thesis of this article is that physicians do not have an analogous conceptual framework for approaching end-of-life care. The authors present and describe a framework for end-of-life care with 3 main elements: control of pain and other symptoms, the use of life-sustaining treatments and support of those who are dying and their families. This 3-part framework can be used by clinicians at the bedside to focus their efforts in improving the quality of end-of-life care.

Dr. H is sitting at home enjoying dinner when the phone rings. The caller is Mr. J, an acquaintance of Dr. H's. He is distraught. He asks how much air must be injected into an intravenous line to cause a person to die. When asked why he wants to know, he explains that his 72-year-old father, currently a patient in a local hospital, has end-stage metastatic lung cancer and is in excruciating pain. Mr. J cannot bear to see his father in such pain and wants to end his suffering by means of an air embolism.

Mr. K, a 68-year-old man with a 100 pack-year history of smoking and known chronic obstructive pulmonary disease, presents to the emergency department with pneumonia and respiratory failure. He has been intubated 4 times before for respiratory failure. He uses oxygen at home and is dyspneic at rest. He has hypoxemia and hypercapnia and is delirious. The emergency physician, Dr. L, tries to stabilize his condition with oxygen, salbutamol, steroids and noninvasive ventilation, but Mr. K's respiratory status worsens. Dr. L cannot locate Mr. K's family. She calls Mr. K's family physician and respirologist to find out whether they have ever discussed re-intubation, but unfortunately neither has done so. Although she is uncomfortable with this situation because of the uncertainty about the patient's wishes, Dr. L decides to perform the intubation.

## What is end-of-life care?

A physician who receives a call from the emergency department to see a patient with heart failure will have a clear concept of what heart failure is, as well as a framework within which to approach the condition and its management. Our thesis in this paper is that physicians do not have an analogous conceptual framework for approaching end-of-life care. Several aspects of end-of-life care are addressed in other articles in this series, especially those on truth telling,[1] consent,[2] capacity,[3] substitute decision-making,[4] advance care planning,[5] euthanasia and assisted suicide,[6] and appropriate use of life-sustaining treatment.[7] Our purpose here is to incorporate these pieces into a coherent conceptual framework that physicians can use to approach the care of patients at the end of life. Our framework, described in greater detail in the section "How should I approach end-of-life care in practice?," has 3 main elements: control of pain and other symptoms, decisions on the use of life-sustaining treatment, and support of dying patients and their families. This article underlines the primary purpose of the "Bioethics for Clinicians" series: "to elucidate key concepts in bioethics and to help clinicians to integrate bioethical knowledge into daily practice. . . . [T]he goal is to support performance: what clinicians actually do."[8]

## Why is end-of-life care important?

### Ethics and law

From an ethical perspective, the principle of beneficence requires that pain and other symptoms be controlled. The legal status of control of pain and other symptoms is not absolutely clear, but physicians should not risk legal peril if they follow established guidelines distinguishing these practices from euthanasia.[9]

Aspects of "life-sustaining treatment" comprise advance care planning, decisions to withhold or withdraw life-sustaining treatment and appropriate use of life-sustaining treatment. Advance care planning is ethically supported by the principle of respect for autonomy and is legally recognized in most Canadian provinces.[5] Decisions by patients or substitute decision-makers to withhold or withdraw life-sustaining treatment proposed by a physician are supported by the ethical principle of respect for autonomy and the legal doctrine of informed consent.[2–4] In contrast, the ethical and legal issues related to appropriate use of life-sustaining treatments demanded by patients and substitute decisions-makers over the objections of physicians are not as clear.[7]

Both euthanasia and assisted suicide are illegal in Canada.[6]

### Policy

Recent policy initiatives have framed end-of-life care as an issue in health care quality — a positive development, in that it focuses organizational commitment to quality on the problem

of end-of-life care. But what does quality end-of-life care entail? In the United States, several organizations have published a "statement of principles" of quality end-of-life care that includes the following domains: treatment of physical and emotional symptoms, support of function and autonomy, advance care planning, aggressive care near death, patient and family satisfaction, global quality of life, family burden, survival time, provider continuity and skill, and bereavement.[10] The Committee on Care at the End of Life of the US Institute of Medicine, National Academy of Sciences, has proposed the following 6 categories of quality end-of-life care: overall quality of life, physical well-being and functioning, psychosocial well-being and functioning, spiritual well-being, patient perception of care, and family well-being and perceptions.[11]

**Empirical studies**

Although euthanasia consumes the attention of the media, the critical ethical issues vexing physicians, patients and families lie elsewhere. In particular, pain is often poorly managed.[12–14] In one study of older patients who were conscious during the last 3 days of life, 4 in 10 had severe pain most of the time.[15] In a survey of physicians and nurses at 5 US hospitals, 47% of respondents reported that they had acted against their conscience in providing care to the terminally ill, and 55% reported that they sometimes felt the treatments they offered patients were overly burdensome.[16]

Consistent with the recent focus of policy efforts, quality improvement strategies have been applied at the organizational level to the problem of end-of-life care.[17,18] For example, in an innovative program called "Dialogue to Action," Jacobson and associates[19] arranged for the next of kin of patients who had died to describe their experiences of end-of-life care to members of the hospital ethics committee. It is likely that appropriate organizational change will require both the elicitation of "actionable reports" — narratives of care that highlight specific clinical areas for improvement — as well as the development of innovative ways to change clinical practice, for instance, by focusing traditional "morbidity and mortality rounds" on quality end-of-life care.

**How should I approach end-of-life care in practice?**

To address this question, we recommend a conceptual framework with 3 main elements: control of pain and other symptoms, decisions on the use of life-sustaining treatments, and support of dying patients and their families. We do not believe that a conceptual framework will magically solve the documented problems in end-of-life care; we do, however, believe that this is an important step.

**Control of pain and other symptoms**

No patient should die in pain or with other treatable symptoms. Indeed, before social, psychosocial and spiritual problems can be properly addressed, good symptom control must first be achieved: it is difficult to contemplate spiritual issues or to reflect on life's accomplishments when in pain or with kidney basin in hand. The undertreatment of pain and other symptoms is well documented, but aside from inadequate training of health

professionals[20,21] the causes are complicated and not well understood. On occasion, physicians may be concerned about balancing good symptom control with the risk of hastening death. Guidelines have been developed to assist physicians in distinguishing appropriate analgesia from euthanasia by lethal injection.[9] Controlling other symptoms, such as nausea, fatigue and breathlessness, may be even more challenging than controlling pain, but effective approaches have been developed.[22]

Physicians must keep in mind that the problems of dying patients have their genesis at an earlier time in the trajectory of illness. Thus, palliative care should not be isolated as simply an end-of-life option; it must be intermeshed with therapies aimed at prolongation of life or cure. As in other areas of medicine, prevention or early control of a symptom is preferable to a rescue attempt on preventable, but now out-of-control, suffering. Every physician who cares for dying patients should ensure that he or she has adequate skills in this domain, as well as access to skilled consultative help from palliative care specialists.

**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[5,23–26] and guide and support the patient and the family through the process of giving consent to treatment and arranging for substitute decision-making.[4] A key skill here is the communication of bad news.[27] In addition, physicians need to develop an approach to the opposite problem — when the patient or the family demands treatment that the physician feels is inappropriate.[5] A key skill here is the ability to negotiate a treatment plan that is acceptable to the patient, the family and the health care team.[28]

**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. Although physicians should be sensitive to the range of psychosocial distress and social disruption common to dying patients and their families, they may not be as available or as skilled as nurses, social workers and other health care professionals in addressing certain issues. An interdisciplinary health care team can help in these areas.

Spiritual issues often come to the fore as one is dying, and pastoral care teams should be available to assist the patient's own clergy in counselling.

Although not all families need or desire follow-up after the death of a loved one, many appreciate a letter or a telephone call from the physician or a member of the palliative care team. Some families will need more specific help. Physicians should be sensitive to risk factors

for poor adjustment to bereavement and should be knowledgeable about local bereavement services.[29]

**The cases**

Both of the cases presented at the beginning of this article represent failures in end-of-life care. In the first, inadequate pain control led to a desire for euthanasia. What was needed was not an air embolism but better pain control. When this was achieved, Mr. J was relieved and did not pursue the idea of euthanasia. This case also illustrates that physicians should not take requests for euthanasia at face value; rather, they should explore and address the problems in end-of-life care that might have led to such requests.

The second case represents a failure of communication about life-sustaining treatments. Mr. K had end-stage lung disease and had been intubated 4 times previously, so he was ideally situated to know whether he wanted to undergo the procedure again; indeed, it is very likely that he had considered this possibility. If he did want intubation, knowledge of his wishes would have relieved Dr. L's anxiety. (Although death was looming, it would be difficult to claim that intubation would be futile in this case, given that it had worked before.) If Mr. K did not want to undergo intubation, he missed his opportunity to communicate this desire. Arguably, the family physician and the respirologist should have broached this issue with him and helped him to make his wishes known in such a way that they would be effectively communicated when respiratory failure occurred.

In summary, physicians caring for patients at the end of their lives should ask themselves 3 questions: Am I managing this patient's pain and other symptoms adequately? Have I addressed the relevant issues with respect to the use of life-sustaining treatment? Am I supporting this person and his or her family?

## Dealing with demands for inappropriate treatment

**Abstract**

Demands by patients or their families for treatment thought to be inappropriate by health care providers constitute an important set of moral problems in clinical practice. A variety of approaches to such cases have been described in the literature, including medical futility, standard of care and negotiation. Medical futility fails because it confounds morally distinct cases: demand for an ineffective treatment and demand for an effective treatment that supports a controversial end (e.g., permanent unconsciousness). Medical futility is not necessary in the first case and is harmful in the second. Ineffective treatment falls outside the standard of care, and thus health care workers have no obligation to provide it. Demands for treatment that supports controversial ends are difficult cases best addressed through open communication, negotiation and the use of conflict-resolution techniques. Institutions should ensure that fair and unambiguous procedures for dealing with such cases are laid out in policy statements.

Mr. A, a 58-year-old man with metastatic cancer, is admitted to hospital because of sepsis. When his physician discusses a do-not-resuscitate order with him, the patient is adamant that he wants to be resuscitated in the event of cardiac arrest.

Mrs. B is a 43-year-old woman in a persistent vegetative state secondary to head trauma suffered in a motor vehicle accident 13 months ago. She and her family are Orthodox Jews. When pneumonia develops, the family insists that "everything be done" for her, including, if necessary, treatment in the intensive care unit.

**What are demands for inappropriate treatment?**

The right of the patient to refuse an unwanted medi-cal intervention, even a life-saving treatment, is a well-established ethical and legal dictum in medicine. The limits of patient autonomy, however, have been challenged recently by demands from patients and families for medical interventions felt by the health care team to be inappropriate. Although treatment demanded by patients runs the gamut of medical interventions, the most pressing cases involve appeals for life-sustaining treatment. Must clinicians always accede to the wishes of patients and families? Are all such cases more or less similar, or are important moral distinctions among cases to be drawn?

A number of approaches to the problem have been proposed. Perhaps best known is that of "medical futility." The concept was devised to take "precedence over patient autonomy and [permit] physicians to withhold or withdraw care deemed to be inappropriate without subjecting such a decision to patient approval."[1] According to this view, a treatment is quantitatively futile "when physicians conclude (either through personal experience, experiences shared with colleagues, or consideration of reported empiric data) that in the last 100 cases, a medical treatment has been useless."[1] A treatment is qualitatively futile if it "merely preserves permanent unconsciousness or . . . fails to end total dependence on intensive medical care."[1] Futile treatment need neither be offered to patients nor be provided if demanded.

Critics of medical futility have argued that it confounds morally distinct cases: demand for treatment unlikely to work, and demand for effective treatment supporting a controversial end (e.g., permanent unconsciousness). They point out that the concept of medical futility is unnecessary in the first case and harmful in the second. Appeals for ineffective treatment can be dismissed because such treatment falls outside the bounds of standard medical care.[2] Cases in which care is effective but the end supported is controversial typically involve substantial value disagreements. An optimal approach to such cases will rest on open communication and negotiation between the health care team and the patient or family.

## Why are demands for inappropriate treatment important?

Demands for inappropriate treatment, although infrequent, cause substantial emotional and moral distress for patients, families and health care workers. In a few cases conflict may be so severe that legal action is taken by either the hospital or the patient.

## Ethics

Medical care is governed by a number of ethical principles, including respect for persons, beneficence, nonmaleficence and justice.[3] These principles find expression in the CMA's *Code of Ethics*.[4] When caring for patients, including those who are receiving (or who may receive) life-prolonging treatments, physicians have an obligation to "[a]scertain wherever possible and recognize [the] patient's wishes about the initiation, continuation or cessation of life-sustaining treatment" and, if the patient is unable to speak for herself, to respect wishes expressed in an advance directive or by a proxy decision-maker (usually a family member).[4] Obligations to respect the wishes of patients, however, must be tempered by duties to "consider first the well-being of the patient" and to provide "appropriate care."[4] Finally, physicians must not discriminate against patients on such grounds as medical condition, disability or religion.[4] Demands for ineffective treatment and demands for effective treatment that supports a controversial end must be considered separately.[5]

## Demands for ineffective treatment

It is uncontroversial that clinicians have no obligation to provide a treatment that cannot work or is very unlikely to work (e.g., an antibiotic to treat a common cold, or mechanical ventilation in the presence of massive tumor deposits in the chest).[5,6] Such treatment falls outside the bounds of "appropriate care." But what of demands for experimental treatment (treatment with an unknown chance of success) when proven treatment exists or treatment is effective but outdated (the success rate is known to be less than that of standard treatment but greater than 1%)? Medical futility provides no basis to refuse these *prima facie* unreasonable requests from patients. Clearly, then, we require a more robust ethical concept.

"Appropriate care" is most productively understood as treatment that falls within the bounds of standard medical practice, that is, medical interventions used by at least a "respectable minority" of expert practitioners.[7,8] Standard of care is a well-established concept rooted in the physician–patient relationship:

> [The] health care professional has an obligation to allow a patient to choose from among medically acceptable treatment options . . . or to reject all options. No one, however, has an obligation to provide interventions that would, in his or her judgment, be countertherapeutic.[9]

Thus, on the basis of standard of care alone, and without appeal to medical futility, clinicians have a sound basis for refusing to provide ineffective, experimental or outdated treatment.

**Demands for effective treatment that supports a controversial end**

Disagreements about so-called qualitatively futile treatment are not about probabilities — they are about values. Often the question "What sort of life is worth preserving?" is at their core. Although most patients and their families would not choose to prolong life in a profoundly diminished state, some have very good reasons for doing so. For example, members of a variety of religions, including Orthodox Judaism, fundamentalist Protestantism, fundamentalist Islam and conservative Catholicism, believe that the sanctity of human life implies a religious obligation to seek out and obtain life-prolonging medical treatment.[10] The concept of medical futility wrongly tries to

> redefine a debate about conflicting values as a debate about medical probabilities. And given that physicians are generally the sole arbiters of medical probability, this amounts to saying to families, "Your values don't count."[11]

A unilateral decision to withhold or withdraw care in such cases violates the obligation to respect the wishes and values of the patient and may constitute discrimination on grounds of physical or mental disability, or religion. Within the constraints of available resources, clinicians must try to deal with such conflicts through open communication and negotiation.

**Cases at the boundary**

Our analysis implicitly rests on the determination of whether a particular treatment falls within the bounds of standard medical care. A variety of factors may be used to argue for a treatment being considered appropriate: the prevalence of its use by expert clinicians (the threshold being its use by at least a "respectable minority"), licensure by Health Canada's Therapeutic Products Directorate for a specific use, and the existence of high-quality scientific evidence of its safety and efficacy.

The gap between scientific evidence and clinical practice is closing because of initiatives in evidence-based medicine, including clinical practice guidelines. Although the correspondence between evidence and practice is currently less than perfect, high-quality evidence of the effectiveness of a treatment may be sufficient to establish that it falls within the bounds of standard care, assuming adequate resources. *A fortiori*, clear evidence that a prevalent treatment is positively harmful or ineffective establishes that the treatment is not appropriate medical care.

**Law**

Although the physician has a legal duty to treat a patient once the physician–patient relationship has been established,[12] this does not imply that the physician must provide any treatment demanded by the patient. Picard and Robertson,[13] in their authoritative book *Legal Liability of Doctors and Hospitals in Canada*, conclude that there is no obligation to inform patients of or to provide them with treatment that is completely ineffective.

Nor is there a duty to provide treatment contrary to the patient's best interests. Manitoba's Court of Appeal recently ruled on a case involving a do-not-resuscitate (DNR) order being challenged by the parents of a 1-year-old child in a persistent vegetative state.[14] The child had been savagely attacked at 3 months of age and afterward had been taken by the Child and Family Services of Central Manitoba. Justice J.A. Twaddle, upholding the lower court's decision to grant the DNR order, commented:

> [I]t is in no one's interest to artificially maintain the life of a . . . patient who is in an irreversible vegetative state. That is unless those responsible for the patient being in that state have an interest in prolonging life to avoid criminal responsibility for the death.[14]

That is, the judge found that the parents were not deciding in the best interests of the child.

A case involving demand for life-prolonging treatment based on deeply rooted cultural or religious beliefs has yet to be considered by Canadian courts, and so the issue remains undecided. Defendant doctors and hospitals are likely to be confronted with a number of well-known cases in the US courts that have sided with families and supported the provision of life-sustaining treatment, but Canadian courts are not necessarily influenced by these decisions.[15] The US cases of Helga Wanglie and Baby K are particularly well known. Both cases involved demands for continued life-prolonging treatments for patients in a persistent vegetative state. In the Wanglie case, the court refused an attempt to have the husband replaced as the decision-maker for his wife.[16,17] In the Baby K case, the court ordered physicians to provide life-prolonging interventions to the child.[18]

In other US cases courts have sided with clinicians. In the Gilgunn case, a jury found that clinicians were not negligent for the death of a patient when they removed mechanical ventilation despite the objections of the patient's daughter.[19] Commentators have questioned whether the court would have sided against the family if the patient were still alive and the continued provision of life-sustaining care were at issue.[20] The decision by the Court of Appeal of Manitoba is consistent with many others in common-law jurisdictions. In a leading English case, for instance, Lord Keith noted the following:

> [A] medical practitioner is under no duty to continue to treat . . . a patient where a large body of informed and responsible medical opinion is to the effect that no benefit would be conferred by continuance.[21]

**Policy**

Issues raised by demands for inappropriate treatment have been dealt with in a number of policy statements.[22–26] All of these policies acknowledge the patient's right to refuse unwanted medical treatment, even life-prolonging treatment. Some of these policies assert that the physician has a right to unilaterally withhold or withdraw treatment that she or he deems futile. For example, the CMA's "Joint statement on resuscitative interventions (update 1995)" states that "[t]here is no obligation to offer a person futile or nonbeneficial treatment"; that is, the treatment "offers no reasonable hope of recovery or improvement or . . . the person is

permanently unable to experience any benefit."[24] The policy was recently criticized on the basis that families of people in a persistent vegetative state may have morally and legally enforceable reasons to demand CPR.[11]

At least one recent policy initiative has shifted away from attempts to define "futility" and has instead focused on the establishment of fair procedures for dealing with demands for inappropriate treatment. This initiative involves a staged approach to such conflicts currently in use in a number of hospitals in Texas.[27] The procedure emphasizes clear communication, negotiation and, if needed, impartial arbitration. The University of Toronto Critical Care Program and Joint Centre for Bioethics have developed a model policy on appropriate use of life-sustaining treatment (www.utoronto.ca/jcb [under "end of life"]).

**Empirical studies**

Decisions to withhold or withdraw life-sustaining treatment are common in modern health care.[28–30] Disagreements over withdrawing life support, a kind of demand for inappropriate treatment, are relatively uncommon and many resolve over time.[28–30] Demands for inappropriate treatment are nonetheless a source of substantial moral and emotional distress for health care workers and patients' families.[31,32] Such requests and the distress they incite arise from a variety of causes, including unrealistic expectations of the family, failure of the clinician to be realistic, lack of clear explanation of the implications of continued treatment and fear of litigation.[33]

**How should I approach demands for inappropriate treatment in practice?**

If the proposed treatment clearly falls outside the bounds of standard medical care, the physician has no obligation to offer or provide it. However, if substantial medical controversy as to the beneficial effect of the treatment exists, the law on this issue is unclear. Furthermore, this assertion does not address the emotions surrounding a case, so a clinician should proceed with caution.

Some of the most difficult cases occur at the boundary of appropriate medical care, when it is unclear whether demanded treatment falls within the standard of care. A treatment may have little evidence to support its safety and efficacy, it may be advocated by a very small group of physicians, or new evidence may have arisen questioning established use. Because patients and their families have increased access to uncontrolled sources of medical information on the Internet, demands for treatment of this sort may increase. In such cases, the physician ought to consult with colleagues within and outside of her institution: How prevalent is the treatment? How respected are those advocating it? Is there evidence for efficacy and safety? Beyond these obvious questions, others will need to be asked by the physician: Am I competent to administer the treatment? Does its provision violate my own conscience or the mission of my institution? A negative response to these last 2 questions calls for the patient to be transferred to the care of another physician or another institution.

Misunderstandings, emotional anguish and disagreements about fundamental values often lie at the heart of cases in which seemingly inappropriate care is demanded. Therefore, the health care team should take a patient, supportive, empathic and open approach in attempting to resolve these cases. Effective communication skills are essential. The physician should ask: Why has the conflict over treatment arisen? What are the deeper issues at stake (e.g., a need for more information, denial, trust, differing values)? Such cases often also lead to conflicts among members of the health care team, and these too should be addressed in an open and constructive manner.

When disagreement among health care providers, patient and family persists, the physician should conceptualize this as a situation of conflict in which the goal is to seek a negotiated solution.[34] If necessary, the physician should seek the services of someone trained in conflict mediation, such as a clinical bioethicist, psychiatrist, psychologist or social worker.

If the conflict cannot be resolved through mediation, arbitration may be necessary. Consultation with a lawyer is important at this stage. Some provinces have provisions in their consent laws for arbitration through boards. For example, the Consent and Capacity Board in Ontario has the power to replace a substitute decision-maker who is not making decisions according to the patient's wishes or best interests.[35] As a final recourse, the courts may be appealed to by either party, but this step runs the risk of increasing both the emotional anguish of patients, family and health care providers, and the conflict among them. Ideally, the health care institution will have a policy on dealing with demands for inappropriate treatment. The policy should describe a clear and nonarbitrary process to address such cases in the institution.[27]

**The cases**

Mr. A has advanced cancer and demands cardiopulmonary resuscitation (CPR). There is good evidence that CPR is very unlikely to be effective for patients with metastatic cancer or sepsis, let alone a patient who has both; therefore, such treatment falls outside the bounds of standard care.[36–39] We have said that, in general, there is no obligation to offer or provide such treatment. Should the decision to withhold CPR be communicated to the patient? We think so. First, the expectation on the part of the patient that CPR will be provided may create an obligation to disclose the fact that it will not be provided and the reasons why.[13] Second, it furthers the end of honesty and open communication with the patient. Third, and perhaps most important, it provides the physician with the opportunity to explore the motivations for the demand. If denial is a factor, counselling may be offered. If control is an issue, the clinician should help the patient focus on the various options that exist regarding his care. Clinicians should remain open to the possibility of compassionate exceptions to withholding CPR. For example, if the patient is motivated by the wish to survive to see a relative who will arrive shortly, a time-limited order to attempt resuscitation may be written.

Mrs. B is in a persistent vegetative state, and her family demands aggressive medical treatment. The disagreement is not about the efficacy of the interventions, but whether they should be

used to prolong a state of permanent unconsciousness. Health care workers should not unilaterally refuse to provide treatment in this case. Compromise should be sought through open communication and negotiation. The scarcity of resources, particularly beds in the intensive care unit, is undoubtedly an issue that must be dealt with in this case (and similar cases). An attempt at compromise may include the provision of a variety of treatments outside of the intensive care unit, perhaps including fluids, nutrition, physiotherapy, supplemental oxygen and antibiotics.

## Conflict of interest in research, education and patient care


### Abstract

A conflict of interest occurs in a situation in which professional judgment 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.


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] Dickens[5] 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 practicing 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, dishonorable or unprofessional" acts or omissions and "conduct unbecoming a physician."[5]

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 interactions 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 behavior." 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. Lexchin[21] has provided an excellent overview of the empirical literature between 1978 and 1993. More recently, Hodges[22] reported on interactions between industry and psychiatry residents, interns and clerks, and Sergeant and associates[23] surveyed residents in family medicine. Campbell and colleagues[24] 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 colleagues[8] 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 collaborators[26] 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 colleagues[24] 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 US[28] 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, Hodges[22] 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 analyze prescribing patterns and physician behavior. 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 associates[36] 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.

## Post-Test

Select the ***best*** answer to each of the following items. Mark your responses on the Answer Form.

1. There is a heated debate about whether health professionals may refuse to provide treatments to which they object on _____ grounds.

a. procedural
b. economic
c. moral
d. practical

2. As shown in this course and the survey it presents, situations can occur that raise a number of questions about the balance of rights and obligations within the doctor–patient relationship. Some of those questions include which of the following: _____.

a. Is it ethical for physicians to describe their objections to patients?
b. Is it ethical for physicians to describe their objections to patients?
c. Should physicians have the right to refuse to discuss, provide, or refer patients for medical interventions to which they have moral objections?
d. All of the above

3. Historically, doctors and nurses have not been required to participate in abortions or assist patients in suicide, even where those interventions are legally sanctioned.

a. True
b. False

4. According to the survey presented in this course, most people believe that health professionals should not have to engage in medical practices about which they have moral qualms.

a. True
b. False

5. The procedures health care professionals were surveyed regarding included: _____.

a. providing abortion for failed contraception
b. administering terminal sedation in dying patients
c. prescribing birth control to adolescents without parental approval
d. All of the above

6. In recent years, several states have passed laws that shield physicians and other health care providers from adverse consequences for refusing to participate in medical services that would violate their consciences.

a. True
b. False

7. The results of the survey presented in this course showed that most physicians believe that it is ethically permissible for doctors to explain their moral objections to patients (_____%).

a. 51
b. 63
c. 77
d. 95

8. It is quite possible that the conflict about conscience clauses in various states in regard to the practice of medicine merely represents the latest struggle with regard to religion in America.

a. True
b. False

9. The survey presented in this course assessed physicians' intrinsic religiosity and religious affiliations. Intrinsic religiosity — the extent to which a person embraces his or her religion as the "master motive" that guides and gives meaning to his or her life— was measured on the basis of agreement or disagreement with two statements: "I try hard to carry my religious beliefs over into all my other dealings in life" and "My whole approach to life is based on my religion." Both statements are derived from Hoge's Intrinsic Religious Motivation Scale and have been validated extensively in previous research

a. True
b. False

10. Another finding of the survey presented in this course was that physicians who were male, those who were religious, and those who had personal objections to morally controversial clinical practices were less likely to report that doctors must disclose information about or refer patients for medical procedures to which the physician objected on moral grounds.

a. True
b. False

11. The religious affiliations of the physicians in the survey were categorized as the following: _____.

a. none (a category that included atheist, agnostic, and none),
b. Protestant
c. other (a category that included Buddhist, Hindu, Mormon, Muslim, Eastern Orthodox, and other).
d. All of the Above

12. Physicians who objected to the three controversial medical practices in the survey, were less likely to report that doctors must present all options and refer patients to other providers

a. True
b. False

13. if patients are concerned about certain interventions for sexual and reproductive health and end-of-life care, they should ask their doctors ahead of time whether they will discuss such options.

a. True
b. False

14. These conflicts might be understood in the context of perennial debates about medical paternalism and patient autonomy. Strong forms of paternalism are based on the assumption that physicians know what is best for their patients and may therefore make decisions without informing their patients of the following: _____.

a. all the facts
b. alternatives
c. risks
d. All of the above

15. Most of the physicians in the surveypresented in this course reported that when a patient requests a legal medical intervention to which the physician objects for religious or moral reasons, it is ethically permissible for the physician to describe the reason for the objection but that the physician must also disclose information about the intervention and refer the patient to someone who will provide it.

a. True
b. False

16. The lack of consensus among physicians about whether referrals to other providers who will offer a controversial treatment should be required mirrors the ambivalence about this point within the field of bioethics.

a. True
b. False

17. Ongoing debates about conscientious objections in medicine should take account of the complex relationships among _____.

a. sex
b. religious commitments
c. health care professional's approaches to morally controversial clinical practices
d. All of the above

18. Female physicians are more supportive of full disclosure and referral than are male physicians, perhaps because many controversial issues in medicine (e.g., abortion, contraception, and assisted reproductive technologies) disproportionately involve the sexual and reproductive health of women.

a. True
b. False

19. One caveat offered by the survey's authors is that physicians' judgments about their general obligations do not necessarily correspond with their judgments about any particular clinical scenario, and we do not know how their judgments about their obligations translate into their actual practices.

a. True
b. False

20. Apparently heeding George Washington's call to "labor to keep alive in your breast that little spark of celestial fire called conscience," physicians, nurses, and pharmacists are increasingly claiming a right to the autonomy not only to refuse to provide services they find objectionable, but even to refuse to refer patients to another provider and, more recently, to inform them of the existence of legal options for care.

a. True
b. False

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