Guideline

Informed Consent

STATUS:	APPROVED
Approved by Council:	September 2011
Amended:	n/a
To be reviewed:	September 2016

This document is intended to guide physicians in Saskatchewan when obtaining consent for medical treatment from patients or their substitute decision makers.

The College of Physicians and Surgeons accepts the document "Consent – A Guide for Canadian Physicians" produced by the Canadian Medical Protective Association as an authoritative statement of the requirements for informed consent. That document, as it existed May, 2011 is attached.

Physicians should use that document as a guide when seeking consent to provide treatment to patients.

The CMPA document is available at

https://www.cmpa-acpm.ca/en/handbooks/-/asset_publisher/TayXf91AzWR2/content/consent-a-guide-for-canadian-physicians

The Canadian Medical Protective Association
L'Association canadienne de protection médicale

Consent

A guide for Canadian physicians

Fourth edition

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Preface to fourth edition

The Canadian Medical Protective Association is pleased to present the fourth edition of the booklet entitled *Consent: A Guide for Canadian Physicians.* This edition serves to update the legal principles contained in earlier editions and also incorporates a number of emerging trends and concepts relating to the law of consent. True to its origins, however, the intent and purpose of the guide remains the same: a primer to assist physicians to better understand and implement into practice the requirements of consent to treatment. It is not meant to cover special issues about consent (such as telehealth or genetics, for example); however, some of these issues are explored in the CMPA's *Information Sheets*. Visit our website at www.cmpa-acpm.ca

Several sections, most notably the sections dealing with emergency treatment, capacity to consent and informed consent, have been amended to reflect legislative and judicial developments. Two new subject matters have been added: "*Patient comprehension*" and "*Informed discharge*."

The section entitled "*Treatment in Canada of U.S. and other foreign residents*" has been revised to reflect the current governing law and jurisdiction agreement based in large part upon the advice and recommendations that appear in the CMPA's *Information Sheet* dated December 2005. It is worthy of note that there are now two proposed forms: one for use by physicians in private practice and the other for use in clinics and other health care facilities.

It is the Association's hope that physicians will find this concise booklet helpful in their practice and in their professional relationships with patients.

May 2006

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Introduction

In the shorter Oxford dictionary, consent is defined as "the voluntary agreement to or acquiescence in what another person proposes or desires; agreement as to a course of action."

In the medical context and as the law on consent to medical treatment has evolved, it has become a basic accepted principle that "every human being of adult years and of sound mind has the right to determine what shall be done with his or her own body." Clearly physicians may do nothing to or for a patient without valid consent. This principle is applicable not only to surgical operations but also to all forms of medical treatment and to diagnostic procedures that involve intentional interference with the person.

That consent to treatment was lacking or inadequate continues to be a frequent claim against physicians. Obviously it is important therefore that physicians be aware of their legal obligations in obtaining consent from patients. It is hoped this booklet will assist in strengthening this awareness. It is not intended as a legal treatise on the subject of consent but rather as a practical guide for physicians in their day-to-day dealings with patients.

Emergency treatment

To the general rule that consent must always be obtained before any treatment is administered, there is an important exception. In cases of medical emergency when the patient (or substitute decision maker) is unable to consent, a physician has the duty to do what is immediately necessary without consent. For the physician to declare any clinical situation an emergency for which consent is not required, there must be demonstrable severe suffering or an imminent threat to the life or health of the patient. It cannot be a question of preference or convenience for the health care provider; there must be undoubted necessity to proceed at the time. Further, under medical emergency situations, treatments should be limited to those necessary to prevent prolonged suffering or to deal with imminent threats to life, limb or health.

Even when unable to communicate in medical emergency situations, the known wishes of the patient must be respected. Therefore, before proceeding, the physician will want to be satisfied there has been no indication in the past by way of Advance Directive or otherwise that the patient does not want the proposed treatment. Further, as soon as the patient is able to make decisions and regains the ability to give consent, a proper and "informed" consent must then be obtained from the patient for additional treatment.

In some provinces, legislation permits the designation of substitute decision-makers to provide or refuse consent on behalf of the incapacitated patient. If the substitute decision-maker is immediately available emergency treatment should proceed only with the consent of that individual.

In urgent situations, it may be necessary or appropriate to initiate emergency treatment while steps are taken to obtain the informed consent of the patient or the substitute decision-maker, or to determine the availability of advance directions. However, the instructions as to whether to proceed or not must be obtained as quickly as practicably possible.

When an emergency dictates the need to proceed without valid consent from the patient or the substitute decision-maker, a contemporaneous record (at the time) should be made explaining the circumstances which forced the physician's hand. If the circumstances are such that the urgency might be questioned at a later date, arranging a second medical opinion would be prudent if possible.

The bottom line:

- When the patient or substitute decision maker is unable to consent and there is demonstrable severe suffering or an imminent threat to the life or health of the patient, a doctor has the duty to do what is immediately necessary without consent. Emergency treatments should be limited to those necessary to prevent prolonged suffering or to deal with imminent threats to life, limb or health. Even when he/she is unable to communicate, the known wishes of the patient must be respected.

Assault and battery

Most legal actions against physicians concerning consent are based on negligence and raise allegations as to the adequacy of the consent discussion with the patient. A claim of assault and battery may, however, be alleged in specific circumstances. A physician may be liable in assault and battery when no consent was given at all or when the treatment went beyond or deviated significantly from that for which the consent was given. Allegations of assault and battery might also be made if consent to treatment was obtained through serious or fraudulent misrepresentation in what was explained to the patient.

Thus, as has happened in various legal actions, it was seen as an assault and battery to carry out an amputation without having received consent to do so; to administer an intravenous anaesthetic agent into the left arm when the patient had specifically forbidden it; to sterilize a patient when consent had been given for a Caesarean section only; to operate on the patient's back when consent had been given only for a procedure on the toe.

In each of these examples, the physicians knew they were proceeding in the medical best interests of the patients and took measures which were clearly medically indicated. However, our courts have repeatedly affirmed that good intentions of the physician cannot be substituted for the will of the patient.

The bottom line:

- A physician may be liable in assault and battery when no consent was given at all, when the treatment went beyond or deviated significantly from that for which the consent was given, or if consent to treatment was obtained through serious or fraudulent misrepresentation in what was explained to the patient.

Types of consent

Consent to treatment may be implied or it may be specifically expressed either orally or in writing. The clinical situation determines the approach required.

Implied consent

Much of a physician's work is done on the basis of consent which is implied either by the words or the behaviour of the patient or by the circumstances under which treatment is given. For example, it is common for a patient to arrange an appointment with a physician, to keep the appointment, to volunteer a history, to answer questions relating to the history and to submit without objection to physical examination. In these circumstances consent for the examination is clearly implied. To avoid misunderstanding, however, it may be prudent to state to the patient an intention to examine the breasts, genitals or rectum.

The foregoing notwithstanding, in many situations the extent to which consent was implied may later become a matter of disagreement. Physicians should be reasonably confident the actions of the patient imply permission for the examinations, investigations and treatments proposed. When there is doubt, it is preferable the consent be expressed, either orally or in writing.

Expressed consent

Expressed consent may be in oral or written form. It should be obtained when the treatment is likely to be more than mildly painful, when it carries appreciable risk, or when it will result in ablation of a bodily function.

Although orally expressed consent may be acceptable in many circumstances, frequently there is need for written confirmation. As physicians have often observed, patients can change their minds or may not recall what they authorized; after the procedure or treatment has been carried out, they may attempt to take the position it had not been agreed to or was not acceptable or justified. Consent may be confirmed and validated adequately by means of a suitable contemporaneous notation by the treating physician in the patient's record.

Expressed consent in written form should be obtained for surgical operations and invasive investigative procedures. It is prudent to obtain written consent also whenever analgesic, narcotic or anaesthetic agents will significantly affect the patient's level of consciousness during the treatment.

Requirements for valid consent

For consent to serve as a defence to allegations of either negligence or assault and battery, it must meet certain requirements. The consent must have been **voluntary**, the patient must have had the **capacity** to consent and the patient must have been **properly informed.**

Voluntary consent

Patients must always be free to consent to or refuse treatment, and be free of any suggestion of duress or coercion. Consent obtained under any suggestion of compulsion either by the actions or words of the physician or others may be no consent at all and therefore may be successfully repudiated. In this context physicians must keep clearly in mind there may be circumstances when the initiative to consult a physician was not the patient's, but was rather that of a third party, a friend, an employer, or even a police officer. Under such circumstances the physician may be well aware that the patient is only very reluctantly following the course of action suggested or insisted upon by a third person. Then, physicians should be more than usually careful to assure themselves patients are in full agreement with what has been suggested, that there has been no coercion and that the will of other persons has not been imposed on the patient.

The bottom line:

- Consent obtained under any suggestion of compulsion either by the actions or words of the doctor or others may be no consent at all and therefore may be successfully repudiated.

Capacity to consent

An individual who is able to understand the nature and anticipated effect of proposed medical treatment and alternatives, and to appreciate the consequences of refusing treatment, is considered to have the necessary capacity to give valid consent. However, there are special circumstances to which particular attention must be given.

Age of consent

The legal age of majority has become progressively irrelevant in determining when a young person may consent to his or her medical treatment. As a result of consideration and recommendations by law reform groups as well as the evolution of the law on consent, the concept of maturity has replaced chronological age. The determinant of capacity in a minor has become the extent to which the young person's physical, mental, and emotional development will allow for a full appreciation of the nature and consequences of the proposed treatment, including the refusal of such treatments.

Legislation in a number of provinces and the territories has codified the law on consent, including the reliance on maturity in assessing a young person's capacity to consent to or refuse medical treatment. Only the Province of Quebec has established a fixed age of 14 years, below which the consent of the parent or guardian or of the court is necessary for the purposes of proposed treatment.

Generally, where the minor patient lacks the necessary capacity, the parents or guardian are authorized to consent to treatment on the minor's behalf. In doing so, the parents or guardian must be guided by what is in the best interests of the minor. This consideration becomes all the more important when the parent or guardian seeks to refuse treatment the physician regards as medically necessary. In these circumstances, there is an obligation on the part of physicians to report the matter to child protection authorities.

The bottom line:

- The determinant of capacity in a minor has become the extent to which the young person's physical, mental, and emotional development will allow for a full appreciation of the nature and consequences of the proposed treatment, including the refusal of such treatments.
- Generally, where the minor patient lacks the necessary capacity, the parents or guardian are authorized to consent to treatment on the minor's behalf, and must be guided by what is in the best interests of the minor.

Mental incapacity / Substitute decision-making

It is well accepted that a person who is incapable to make decisions regarding certain matters might still have sufficient mental capacity to give valid consent to medical treatment. Again, it depends on whether the patient is able to appreciate adequately the nature of the proposed treatment, its anticipated effect and the alternatives. Therefore, many individuals who may be mentally infirm or who have been committed to a psychiatric facility continue to be capable of controlling and directing their own medical care, including the right to consent to treatment or to refuse treatment. It is beyond the scope of this general discussion to comment on the various legal requirements pursuant to mental health legislation, but physicians should be generally familiar with the

applicable mental health legislation in their jurisdiction, particularly with reference to formal capacity assessments necessary to declare the patient incapable of consent and the appeal process available to the patient.

In circumstances where it has been determined that a patient is incapable of consenting to a particular medical treatment, the question as to who is authorized to make the decision will arise. It is now possible in the majority of provinces for a patient to execute an Advance Directive as to future care in the event that the patient becomes incapacitated or is unable to communicate his or her wishes. Advance Directives are sometimes referred to as living wills. Advance Directives may contain explicit instructions relating to consent or refusal of treatment in specified circumstances. In some provinces, Advance Directives may be contained in Powers of Attorney for personal care. An Advance Directive may also be used to appoint or designate an individual who will be authorized to make substitute decisions about consent or refusal of treatment in the event that the patient becomes incapacitated. Again, physicians will want to be generally familiar with any applicable legislation in their particular jurisdiction.

A number of provinces have also enacted legislation for substitute decision-makers which sets out and ranks a list of individuals, usually family members, who are authorized to give or refuse consent to treatment on behalf of an incapable person. The specific legislation in the jurisdiction will generally set out the principles that should guide the substitute decision-maker's treatment decision. Generally speaking, substitute decision-makers must act in compliance with any prior capable wish of the patient, where possible. Consideration of such factors as the individual's current wishes and his or her known beliefs and values may also be required, depending on the jurisdiction. It is clear that the substitute decision-maker should always be guided by the patient's best interests. Substitute consent, including that of a parent for a child, cannot be utilized for proposed treatment which might be regarded as non-therapeutic, such as non-therapeutic sterilization. Physicians will want to be alert to other circumstances that might raise unique issues such as substitute consent in the context of clinical research.

> An individual who is able to understand the nature and anticipated effect of proposed medical treatment and alternatives, and to appreciate the consequences of refusing treatment, is considered to have the necessary capacity to give valid consent.

The determination of the patient's best interests, or whether a proposed treatment is "therapeutic" or not can be difficult, and, in circumstances where there are questions or doubts, physicians are encouraged to consult with other physicians and legal counsel. There may be circumstances where an ethical consult would be prudent. Physicians should also be aware that there are legal mechanisms available to address circumstances where concerns exist that a substitute decision-maker may not be acting in the patient's best interests.

In the absence of a valid Advance Directive or duly authorized substitute decision-maker, strictly speaking only the court or someone appointed by the court may properly consent to or refuse medical treatment where the patient lacks the requisite capacity to make the decision. Unfortunately, the legal procedure for the appointment of a guardian of the patient can be lengthy and expensive. As a result, and from a practical standpoint, physicians have often proceeded on the basis of the family's approval where the medical treatment is clearly required, where the patient's condition may deteriorate if not treated promptly, and the treatment is determined to be in the patient's best interests. Should there be any disagreement among family members, or if the proposed treatment carries significant risks, then specific legal advice should probably be sought about that situation.

The bottom line:

- Many individuals who may be mentally infirm or who have been committed to a psychiatric facility continue to be capable of controlling and directing their own medical care, including the right to consent to treatment or to refuse treatment; legal requirements vary with jurisdiction, so physicians should be generally familiar with the applicable mental health legislation in their jurisdiction.
- In circumstances where there are questions or doubts about what is in the patient's best interests or whether a proposed treatment is "therapeutic" or not, physicians are encouraged to consult with other physicians and, when warranted, legal counsel.

Disclosure of information

For consent to treatment to be considered valid, it must be an "informed" consent. The patient must have been given an adequate explanation about the nature of the proposed investigation or treatment and its anticipated outcome as well as the significant risks involved and alternatives available. The information must be such as will allow the patient to reach an informed decision. In situations where the patient is not mentally capable, the discussion must take place with the substitute decision maker.

The obligation to obtain informed consent must always rest with the physician who is to carry out the treatment or investigative procedure. This obligation may be delegated in appropriate circumstances (to a PGY trainee for example) but before assigning this duty to another, the treating physician should be confident the delegate has the knowledge and experience to provide adequate explanations to the patient.

In special circumstances, an obligation of pre-treatment disclosure may fall to more than one physician involved in the care. For example, a radiologist carrying out an invasive diagnostic procedure would likely be seen as responsible for explaining how the test will be done and the risks attendant upon it. The physician who ordered the test might also be expected to tell the patient, in general terms, about the nature and purpose of the test and alternatives which might be employed.

The bottom line:

- The patient must have been given an adequate explanation about the nature of the proposed investigation or treatment and its anticipated outcome as well as the significant risks involved and alternatives available.
- The obligation to obtain informed consent must always rest with the physician who is to carry out the treatment or investigative procedure.

Standard of disclosure

Although obtaining a valid consent from patients has always involved explanations about the general nature of the proposed treatment and its anticipated effect, the Supreme Court of Canada, over two decades ago, imposed a more stringent standard of disclosure upon physicians. The adequacy of consent explanations is to be judged by the "reasonable patient" standard, or what a reasonable patient in the particular patient's position would have expected to hear before consenting.

The Supreme Court of Canada has set out in general terms the scope of the physician's duty in informing patients before treatment as follows:

> *"In summary, decided cases appear to indicate that in obtaining the consent of a patient for the performance upon him of a surgical operation, a surgeon, generally, should answer any specific questions posed by the patient as to the risks involved and should, without being questioned, disclose to him the nature of the proposed operation, its gravity, any material risks and any special or unusual risks attendant upon the performance of the operation. However, having said that, it should be added that the scope of the duty of disclosure and whether or not is has been breached are matters which must be decided in relation to the circumstances of each particular case."*

In a subsequent decision, the court extended the obligation of disclosure as follows:

> *"... a surgeon must also, where the circumstances require it, explain... alternative means of treatment and their risks."*

The foregoing does provide physicians with a general basis for deciding the nature and extent of the pre-treatment information which should be given to patients but it can be difficult to apply legal generalizations to specific clinical situations. Therefore, some comment about several of the points raised in these precedent-setting judgments may be helpful.

Throughout these and other legal judgments which have been rendered in more recent years, there is repeated reference to the need to disclose "material" risks to patients. However, there can be some understandable uncertainty as to what in fact does constitute a "material" risk. One court has defined it as follows:

> *"A risk is thus material when a reasonable person in what the physician knows or should know to be the patient's position would be likely to attach significance to the risk or cluster of risks in determining whether or not to undergo the proposed therapy."*

Thus the particular circumstances of the patient are an important determinant of materiality.

It is clear that the materiality of a risk is influenced as well both by the frequency of the possible risk and also by its seriousness should it occur. Generally speaking, the more frequent the risk, the greater the obligation to discuss it beforehand. Further, even uncommon risks of great potential seriousness should be disclosed. In this context the Supreme Court of Canada indicated that even if a risk is "a mere possibility" yet it carries with it serious consequences such as paralysis or death, it should be regarded as material and therefore requires disclosure.

The bottom line:

- The adequacy of consent explanations is judged by the "reasonable patient" standard, or what a reasonable patient in the particular patient's position would have expected to hear before consenting.
- Recent legal judgments repeatedly refer to the need to disclose "material" risks to patients. Generally speaking, the more frequent the risk, the greater the obligation to discuss it beforehand. Further, even uncommon risks of great potential seriousness should be disclosed.

Patient comprehension

It has been suggested that not only must the physician provide the necessary details about the nature, consequences and material risks of the proposed treatment in order to obtain informed consent, but also the physician has the duty to ensure the patient has understood the information. **This interpretation of the case law goes too far and would place an unfair and unreasonable burden on the physician.** In rejecting this obligation, the court, in a recent Scottish case, commented that such an onus upon the physician could only be discharged through "vigorous and inappropriate cross-examination" of the patient.

There is no doubt, however, that the physician does have a duty to take reasonable steps so as to be relatively satisfied that the patient does understand the information being provided, particularly where there may be language difficulties or emotional issues involved. What amounts to "reasonable steps" will very much depend on the individual facts and circumstances of the particular situation.

It seems clear that by engaging in personal dialogue with the patient, the physician will be placed in the best possible position to be reasonably comfortable the patient understands the consent explanation. Personal attendance permits the physician the opportunity to observe the patient's reaction for signs of apparent comprehension or confusion. As well, the ability of the patient to ask questions will often assist the physician to assess the level of patient understanding.

The bottom line:

- Physicians have a duty to take reasonable steps so as to be relatively satisfied that the patient does understand the information being provided, particularly where there may be language difficulties or emotional issues involved.

Consent disclosure in research and experimentation

The issue of consent merits careful consideration by those physicians who may become involved in any research work in which patients or human volunteers are asked to participate.

In terms of the extent to which risks must be disclosed, there is now less distinction between "therapeutic" and "non-therapeutic" research than in earlier years when requirements for informed consent were less stringent. These days, for any treatment or procedure that is innovative or that could be perceived as experimental, anything which may be interpreted as going beyond the need for prophylaxis, diagnosis or therapy, an element of "research" should be assumed. In such circumstances a standard of full disclosure may be applicable when obtaining consent. The concept of therapeutic privilege is inappropriate and no information about a project or clinical trial may be hidden from a patient on the ground that disclosure would result in undue worry or anxiety. As well, researchers must recognize the potential for what might later appear to have been duress or coercion. This is a particularly important consideration if the subject has a physician-patient relationship with a member of the research team.

A fair explanation must always be given about what is proposed, its risks and discomforts, what, if any, benefits might accrue and, if applicable, what appropriate alternative treatments or procedures might be offered. If a blind study is involved, patients must be aware they could stand to derive no benefit at all. Researchers should offer and make themselves available to answer enquiries about what is proposed and should emphasize to patients or subjects they are free to withdraw consent and discontinue participation in the project at any time without prejudice.

It might be argued that minors or adults with mental disability do not have the capacity to consent when research or experimentation figure to any significant extent in clinical management. Physicians should exercise a great deal of caution in dealing with such situations.

The bottom line:

- When it comes to research and experimentation, a fair explanation must be given about what is proposed, its risks and discomforts, what if any benefits might accrue and, if applicable, what appropriate alternative treatments or procedures might be offered. If a blind study is involved, patients must be aware they could stand to derive no benefit at all.

Informed refusal

Our courts have reaffirmed repeatedly a patient's right to refuse treatment even when it is clear treatment is necessary to preserve the life or health of the patient. Justice Robins of the Ontario Court of Appeal explained:

> *"The right to determine what shall, or shall not, be done with one's own body, and to be free from non-consensual medical treatment, is a right deeply rooted in our common law. This right underlines the doctrine of informed consent. With very limited exceptions, every person's body is considered inviolate, and, accordingly, every competent adult has the right to be free from unwanted medical treatment. The fact that serious risks or consequences may result from a refusal of medical treatment does not vitiate the right of medical self-determination. The doctrine of informed consent ensures the freedom of individuals to make choices about their medical care. It is the patient, not the physician, who ultimately must decide if treatment — any treatment — is to be administered."*

However, difficulty may arise if it should later be claimed the refusal had been based on inadequate information about the potential consequences of declining what had been recommended. In the same way as valid consent to treatment must be "informed," so it may be argued a refusal must be similarly "informed." Physicians thus may be seen to have the same obligations of disclosure as when obtaining consent, that is, disclosure of the risk to be accepted.

When patients decide against recommended treatment, particularly urgent or medically necessary treatment, discussions about their decision must be conducted with some sensitivity. While recognizing an individual's right to refuse, physicians must at the same time explain the consequences of the refusal without creating a perception of coercion in seeking consent. Refusal of the recommended treatment does not necessarily constitute refusal for all treatments. Reasonable alternatives should be explained and offered to the patient.

As when documenting the consent discussion, notes should be made about a patient's refusal to accept recommended treatment. Such notes will have evidentiary value if there is any controversy later about why treatment was not given.

The bottom line:

- Our courts have reaffirmed repeatedly a patient's right to refuse treatment even when it is clear treatment is necessary to preserve the life or health of the patient. Physicians must at the same time explain the consequences of the refusal without creating a perception of coercion in seeking consent.

Informed discharge

Although not strictly an element of the pre-operative consent process, the courts have recently elaborated on the duty or obligation of physicians to properly inform patients in the post-operative or post-discharge period. Thus a physician must conduct a discussion with a patient of the post-treatment risks or complications, even statistically remote ones that are of a serious nature. The purpose is to inform the patient of clinical signs and symptoms that may indicate the need for immediate treatment such that the patient will know to visit the physician or return to the hospital/facility.

The bottom line:

- Physicians have an obligation to properly inform patients in the post-operative or post-discharge period, most specifically about clinical signs and symptoms that may indicate the need for immediate treatment.

Some practical considerations about informed consent

The law on consent will continue to evolve. However, current interpretation of legal judgements dealing with "informed consent" will allow some suggestions which may be of practical assistance to physicians in their attempt to meet the legal standards:

1. Insofar as may be possible, tell the patient the diagnosis. If there is some uncertainty about the diagnosis mention this uncertainty, the reason for it and what is being considered.
2. The physician should disclose to the patient the nature of the proposed treatment, its gravity, any material risks and any special risks relating to the specific treatment in question. Even if a risk is a mere possibility which ordinarily might not be disclosed, if its occurrence carries serious consequences, as for example paralysis or death, it must be regarded as a material risk requiring disclosure.
3. A physician must answer any specific questions posed by the patient as to the risks involved in the proposed treatment. Always the patient must be given the opportunity to ask questions.
4. The patient should be told about the consequences of leaving the ailment untreated. Although there should be no appearance of coercion by unduly frightening patients who refuse treatment, our courts now recognize there is a positive obligation to inform patients about the potential consequences of their refusal.
5. The patient should be told about available alternative forms of treatment and their risks. There is no obligation to discuss what might be clearly regarded as unconventional therapy but patients should know there are other accepted alternatives and why the recommended therapy has been chosen.
6. Physicians must be alert to a patient's individual concerns about the proposed treatment and deal with them. It must be remembered that any particular patient's special circumstances might require disclosure of potential although uncommon hazards of the treatment when ordinarily these might not be seen as material. Courts have made it clear that the duty of disclosure extends to what the physician knows or should know the particular patient deems relevant to a decision whether or not to undergo treatment.
7. Although any particular patient may waive aside all explanations, may have no questions, and may be prepared to submit to the treatment whatever the risks may be without any explanatory discussion, physicians must exercise cautious discretion in accepting such waivers.
8. When, because of emotional factors, the patient may be unable to cope with pre-treatment explanations, the physician may be justified in withholding or generalizing information which otherwise would be required to be given. This so-called "therapeutic privilege" should be exercised with great discretion and only when there are compelling reasons dictated by clinical circumstances.
9. In obtaining consent for cosmetic surgical procedures or for any type of medical or surgical work which might be regarded as less than entirely necessary to the physical health of the patient, physicians must take particular care in explaining fully the risks and anticipated results. As in experimental research situations, courts may impose on physicians a higher standard of disclosure in such circumstances.
10. Encouragement about optimistic prospects for the results of treatment should not allow for the misinterpretation that results are guaranteed.
11. Where a part or all of the treatment is to be delegated, patients have a right to know about this and who will be involved in their care. Consent explanations should include such information.
12. A note by the physician on the record at the time of consent explanations can later serve as important confirmation that a patient was appropriately informed, particularly if the note refers to any special points which may have been raised in the discussion.

A consent form itself is not consent

Consideration of a consent form to be signed by the patient should not obscure the important fact that the form itself is not the "consent." The explanation given by the physician, the dialogue between physician and patient about the proposed treatment, is the all important element of the consent process. The form is simply evidentiary, written confirmation that explanations were given and the patient agreed to what was proposed. A signed consent form will be of relatively little value later if the patient can convince a court the explanations were inadequate or, worse, were not given at all.

Apart from providing evidence that a patient consented to proposed treatment, there is another important reason for having consent forms signed. In many Canadian jurisdictions it has become a legal requirement that such a document must be completed before any surgical procedure is undertaken in a hospital.

The bottom line:

- The explanation given by the physician, the dialogue between physician and patient about the proposed treatment, is the all important element of the consent process.
- The consent form itself is not the "consent." It is simply evidentiary, written confirmation that the explanations were given and that the patient agreed to what was proposed.
- In many Canadian jurisdictions it has become a legal requirement that such a document must be completed before any surgical procedure is undertaken in a hospital.

Basic elements

On the basis of experience in advising and defending its members on matters of consent, the Canadian Medical Protective Association believes a satisfactory consent form, adaptable to most situations, should be a relatively simple document, such as the prototype suggested on page 13.

Identification and acknowledgement of explanations

The form should name the patient and in general terms the nature of the investigation, treatment or operation. It should name the physician who is to carry out the treatment. There should be included an acknowledgement by the patient that explanations have been given about the nature of the treatment and its anticipated effect, and about any material risks and special or unusual risks. Mention should be made also of the patient's acknowledgement that alternative forms of treatment or investigation have been discussed. The form should allow for acknowledgement by the patient that he or she is satisfied with the explanations and has understood them.

Anaesthesia

Again, as a result of its experience with negligence litigation against physicians, the Canadian Medical Protective Association continues to believe that specific consent, except where required by a statute, is unnecessary for the administration of anaesthesia for surgery. The need for written consent for anaesthesia is seen as limited because ordinarily it should be implicit in the documentation of the pre-anaesthetic examination by the anaesthetist that the patient was properly informed. The pre-anaesthetic visit by the anaesthetist or the anaesthetist's delegate provides an opportunity for discussion about alternative forms of anaesthesia which might be offered, any exclusions imposed by the patient and any particular risks which the examining anaesthetist feels may be appropriate to mention in the particular case.

Although usually the record of the pre-anaesthetic examination will adequately confirm the dialogue which occurred between anaesthetist and patient, if specific consent for anaesthesia is included on a form, care should be taken to avoid provision on the document inviting exclusions to be stated by the patient. Any such exclusions should have been agreed upon at the pre-anaesthetic examination. Failing such discussion and decision, and particularly with a form that offers opportunity for the patient to stipulate exclusions, there is greater risk the patient could impose last minute restrictions on the anaesthetist with the possibility that these might be overlooked.

Added or alternative procedures

The clause in the prototype form authorizing additional or alternative procedures requires some special comment. In their pre-operative explanations to patients, surgeons will always attempt to anticipate in advance what various conditions might be encountered and what alternative procedures might have to be added during the operation. However, not infrequently, circumstances arise which compel the physician to consider an extension of the procedure, something which could not have been anticipated and which was not mentioned to the patient beforehand.

In these situations, the physician may exceed the mandate given by the patient only if failure to take the

additional or alternative steps would render ineffective the procedure for which the consent was given or would pose a significant risk to the health or life of the patient. If there arises need to proceed with something wholly different from that to which the patient has given consent and if it be reasonable and not harmful to delay, the patient should be allowed to regain consciousness. Then additional explanations can be given and consent sought for the different procedure. Only when something additional or alternative is immediately necessary and vital to the health and life of the patient, not merely a matter of convenience, should a physician proceed without expressed consent.

Delegation to others

The final paragraph of the prototype consent form is deemed necessary because of two sets of circumstances which are common in practice. The first is the situation where a number of physicians work as a group and where for various reasons work may be delegated to another member of the same group.

The other circumstances are those found in teaching hospitals where PGY trainees and others participate in the care of patients. Delegation of work and responsibility to these post-graduate trainees is essential. They must have assigned to them increasing responsibility for reaching decisions and for carrying out progressively more difficult and complex treatments and procedures once they have shown evidence of ability.

Patients must be informed about the involvement of trainees in their care. At the same time they should be reassured about the quality of that care and the measure of supervision which will be exercised. If patients in teaching hospitals are told that other physicians may be involved in their care, if they are given appropriate reassurances and especially if they have already met the other members of the medical team looking after them, patients will likely accede to the proposals and, most important, can never claim they did not know work might be delegated to someone else.

Some clinical teachers may still have concern that if all of this is done routinely and such acknowledgements are set out on a consent form, some patients might refuse to allow the management to be delegated, insisting that their own attending physician provide it all. This, of course, is the patient's prerogative. If there must be difficulty, better it be resolved beforehand than to be faced later with a patient who thinks the result of treatment is less than ideal and who then claims if it had been known the treatment was to be delegated, consent would have been withheld. Under such circumstances both physician and post-graduate trainee might be relatively defenceless.

Signatures and witnesses

Remembering that consent forms are simply documentary confirmation of consent explanations and the patient's willingness to proceed with what has been proposed, it is preferable to arrange for a patient's signature on the form as contemporaneously as possible with the pre-treatment discussions. Sometimes it is convenient to accomplish this in a physician's office or at the bedside with the physician present. More often, however, the signing may occur as an administrative step during the process of admission to hospital or as part of a hospital ward administrative routine. The patient should be given ample opportunity to consider what he or she is signing and be given adequate opportunity to consider the implications of that to which they are consenting.

Because of the varying circumstances under which consent forms are frequently signed, nurses or other hospital personnel may be asked to witness the signing. It should be remembered that in witnessing a signature the witness simply confirms the identity of the patient who signed the document and that the person's mental state at the time appeared to allow for an understanding of what was signed. The role of the witness has no other legal significance. Most important, the witness to a signature on a consent form should not feel he or she has any obligation whatsoever to provide pre-treatment explanations which, in signing the form, the patient acknowledges having received. A nurse or other person witnessing a patient's signature on a consent form does in no way attest to the adequacy of explanations which have been given by the physician. However, if a patient implies or states that he or she has been inadequately informed about the nature of the proposed treatment, a person witnessing the signature or others present should not press for the signature and the treating physician should be notified.

Some consent forms require the signature of the treating physician who, by signing, acknowledges that consent explanations have been given. Clearly, the purpose of this signature is to direct the physician's attention to his or her legal obligations. Although the purpose of the treating physician's signature may be commendable, having regard to some of the practical considerations in arranging for the completion of consent forms, it may be preferable that this requirement not be contained on the form and imposed. On most occasions the physician will

have held the required discussions with the patient previously and may not be readily available at the time when the form is prepared for the patient's signature. Then, if through an administrative failure the physician's signature fails to appear on the form, its absence might be more harmful to the physician's legal interest than if the form did not call for his or her signature in the first place.

Notes in the medical record

A signed consent form has undoubted evidentiary value and is a specific legal requirement in many situations. However, when an informed consent is called into question, a physician's note on the record may be of equal or even greater usefulness for defence purposes. Courts rely heavily on progress notes if it is clear they were made contemporaneously with the events they record.

At the time when consent explanations are given it is a relatively simple matter for the physician to note briefly some of the significant points raised in conversation with the patient. Such notations, particularly if they identify questions or special concerns expressed by the patient, can serve to validate the consent process better than any other documentation.

The note need not be voluminous or time consuming. If it records on the office or hospital chart something relevant to the discussion with the particular patient, it will be much more credible in evidence than the recollections of any of the parties involved in a lawsuit. The contemporaneous progress note about consent can be invaluable and is highly recommended.

Basic elements of a consent form: Consent to investigation, treatment or operative procedure

(1) I,_____, hereby consent to undergo the investigation, treatment or operative procedure, _____, ordered by or to be performed by Dr._____.

(2) The nature and anticipated effect of what is proposed including the significant risks and alternatives available have been explained to me. I am satisfied with these explanations and I have understood them.

(3) I also consent to such additional or alternative investigations, treatments or operative procedures as in the opinion of Dr._____are immediately necessary.

(4) I further agree that in his or her discretion, Dr._____may make use of the assistance of other surgeons, physicians, and hospital medical staff (including trainees) and may permit them to order or perform all or part of the investigation, treatment, or operative procedure, and I agree that they shall have the same discretion in my investigation and treatment as Dr. _____.

Dated_____
day / month / year

Witness_____

Patient_____

Handouts and materials supplemental to consent explanations

Because the essential element of consent is the dialogue and sharing of information between physician and patient, anything which can conveniently facilitate this process is desirable. The pre-treatment consent discussions with the patient are most important and should not be replaced; however, sometimes these discussions can be more informative if they are supplemented by printed or other recommended materials which are given to the patient in advance and can be reviewed at leisure by the patient.

For relatively standardized treatments, investigative or therapeutic procedures, background information about what is being proposed may be provided in the form of, for example, information sheets, printed brochures or electronic resources. This material should outline the nature of the proposed treatment or procedure, its purpose and intended outcome, and should mention significant risks and potential complications which might be of relevance to most patients. Such information resources should invite questions from the patient about the treatment and it should be clear that opportunity will be given for such questioning and for further discussion after the resource has been reviewed.

Information sheets, brochures, and similar materials may not be applicable in many circumstances under which consent is obtained but when they are used should be seen only as an adjunct and not a substitute to consent discussions. Frequently consent explanations must be tailored to the particular circumstances of the individual patient.

Because of the wide variety of circumstances under which consent forms are signed, it is preferable that the information sheet or similar document not be an integral part of the consent form. The signing of a consent form, the acknowledgement that appropriate information has already been given, is often simply an administrative step which does
not allow for adequate review of information on which patients must base their decisions for or against treatment. Documents supplementary to consent explanations should be provided well in advance of signing. From time to time when commenting about consent procedures, courts have made it clear, except in urgent and pressing circumstances, patients must be given adequate opportunity to consider the implications of that to which they are consenting.

Consent explanations are sometimes added to in a more elaborate fashion by a videotape recording of the discussion about the proposed treatment or procedure. This adjunct is probably most applicable for cosmetic surgery but may be suitable also in other circumstances.

Regardless of what supplementary methods are employed to provide patients with information prior to consent, it must again be emphasized they can only supplement and not replace dialogue with the patient. For evidentiary purposes, a contemporaneous notation should be made confirming that the supplementary material had been provided and that after reviewing it the patient was given an opportunity to ask questions about it before consenting.

Since legal actions often arise many years after clinical treatment, it is wise to keep older versions of information sheets or other materials in an archive file, with the dates noted of when these were in use,in case they are required during medico-legal difficulties that arise after they are no longer in use.

Regardless of what supplementary methods are employed to provide patients with information prior to consent, it must again be emphasized they can only supplement and not replace dialogue with the patient.

The bottom line:

- Handouts and materials should be supplemental to consent explanations; the essential element of consent is the dialogue and sharing of information between physician and patient.
- Supplementary documents should be provided well in advance of signing the consent form so that patients have adequate opportunity to consider the implications of that to which they are consenting.
- It is wise to keep older versions of materials in an archive file.