Consent to Medical Treatment: The Use of Consent Forms

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William R. Hearn*

Introduction

The use of consent forms without a full understanding of the law of consent to medical treatment is fraught with risk. This is a complicated area of law, which is derived from both the common law and statutes. Particularly in the last decade, the law on consent to medical treatment has been the subject of much judicial and scholarly comment, including, in Ontario, calls and proposals for comprehensive and uniform legislation. As a partial response to this growing concern, on May 27, 1991, the Ontario government introduced Bill 109 (the proposed Consent to Treatment Act), which received second reading on June 20, 1991.

A. An Overview of the Law on Consent to Medical Treatment and the Use of Consent Forms

The law on consent to medical treatment stems from the well-established basic principle that every human being of adult years and sound mind has the right to determine what shall be done with his or her own body. Therefore, in law, it is incumbent upon the attending physician to obtain a valid consent before treating a patient, subject to certain limited exceptions such as when the facts of a case permit the physician to act in a medico-legal emergency or, arguably, to exercise therapeutic privilege. It should be noted that the attending physician cannot delegate responsibility for the consent process and, consequently, delegates tasks related to it at his or her peril.

Generally speaking, consent may be implied from the circumstances or expressed either verbally or in writing. In many instances, implied or oral consent is sufficient. However, in certain cases, the express written consent of the patient is not only preferred, but legally required. For instance, a signed consent is legally required for consent to surgery in a public hospital in Ontario.

It must be stressed that consent to treatment is a process, not simply a signed piece of paper. The “consent” refers to the full pre-treatment dialogue and exchange of information about the proposed treatment between the attending physician and the patient, resulting in the patient’s informed concurrence to the treatment. The patient’s consent to be treated is not achieved by way of the form itself; rather, the form is only documentary evidence of the consent process. This observation, while rather trite, must not be overlooked and, however administratively inconvenient, consent forms should never be used as a substitute for the consent process.

Unless specifically required by legislation, a signed consent form is not the only way to document the consent process. Other ways include: (a) making a detailed handwritten note of the consent in the patient’s medical record; (b) using what is called a consent checklist in a patient interview; and (c) in the case of mass treatments (for example, immunizations), using posted signs, literature and interview booths setting out and explaining to patients the details of the proposed treatment.

A signed consent form gives some legal protection to the hospital and its physicians, nurses and other health care providers should they later be sued by the patient for assault and battery or negligence where the patient alleges lack of informed consent. In addition to civil action, failure to obtain a valid consent to treatment may be the basis for revoking medical staff privileges at the hospital or taking disciplinary proceedings against the attending physician through The College of Physicians and Surgeons of Ontario. Consent documentation is also clinically useful to the attending physician and hospital as an historical record of the patient’s understanding of his or her health care.

B. The Requirements for a Valid Consent

For a patient’s consent to treatment to be valid, the following minimum requirements must be met:

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1. The Patient Must Be Both Competent and Capable to Consent

The patient must be both legally competent to consent to the treatment and possess the mental capacity to authorize the case. In general, any individual who is able to understand the nature and anticipated effect of the proposed treatment and the alternatives, including the consequences of no treatment, is competent to give a valid consent.7

The question of competence is of particular concern in connection with the treatment of minors. The common law supports the view that the age of consent to certain kinds of medical treatment is not necessarily the age of majority. Rather, it is what might be called the age of discernment, which is determined by the minor patient’s ability to comprehend explanations relating to the nature and potential consequences of treatment and not arbitrarily by his or her chronological age. Judicial decisions indicate that the ability of a minor to consent to certain medical treatment depends on his or her personal maturity and intellectual capacity and on the seriousness of the proposed treatment.8

However, the regulations under the Public Hospitals Act controlling the practice of public hospitals in Ontario limit their ability to give full effect to the common law rights which a minor may have. Under the so-called Hospital Management Regulation, no surgical operation shall be performed on a patient under 16 years of age without a consent in writing duly signed by one of the persons noted in the regulation as having the capacity to give substitute consent (such as the minor’s parent, guardian or next-of-kin).9 The regulation also applies to the nonsurgical situation (that is, a diagnostic test or medical treatment) where the attending physician, dentist or administrator of the hospital is of the opinion that a consent in writing should be obtained. The interplay between the mature minor rule at common law and the chronological age requirement under the Hospital Management Regulation leads to odd results. For instance, it is quite possible for a patient under the age of 16 to be legally able to consent to treatment in a physician’s office, but not able to consent to the same treatment by the same physician in a public hospital.10

It should be noted that under section 8 of Bill 109, a person 16 years of age or more is presumed capable of consenting and a person less than 16 years of age is presumed incapable, but both presumptions may be rebutted.

The question of capacity is, like that of competence, the subject of much judicial and statutory gloss. The courts have long recognized that a person suffering from mental illness or incompetence may still retain, in certain circumstances, the mental capacity to give valid consent to treatment. When the adult patient is not able to give a valid consent, the court, or someone appointed by the court, or otherwise authorized by statute, may consent to the treatment on the patient's behalf. When such substitute consent is given, it is limited to proposed treatment that is clearly in the best interests of the patient.

The current legal requirements regarding court approvals often result in delay and expense and there has long been talk of legislation in Ontario to allow a competent patient to designate an individual, perhaps by way of a durable power of attorney for health care, who could be empowered to give substitute consent to medical treatment in the event the patient becomes mentally incompetent.11 In part addressing this point, on May 27, 1991, the Ontario government introduced Bill 108 (the proposed Substitute Decisions Act) and Bill 109 as companion legislation, together with Bill 74 (the proposed Advocacy Act introduced in the Legislature on April 18, 1991).12

2. The Consent Must be Given Voluntarily

The authorization by the patient must be obtained free of any undue influence, coercion or misrepresentation of material information. In this regard, the attending physician must be particularly vigilant that the patient is not the victim of an overbearing third party (such as a friend or employer) who, against the patient’s wishes, might be insisting that the patient seek medical attention.13

3. The Consent Must be Specific and Informed

The patient may consent to treatment
only after having received proper and full disclosure of certain specific information from the attending physician. This information must include an adequate explanation of the proposed treatment (such as its nature, intended purpose, effect and gravity), the material and special or unusual (that is, significant) risks and benefits involved, the available and least restrictive (that is, reasonable) alternatives to the proposed treatment, and the consequences of foregoing treatment. While the consequences of leaving the ailment untreated should be discussed, this must be done without unduly frightening the patient, so as to vitiate the voluntariness of the consent.

In essence, the dialogue between the attending physician and the patient must permit the patient to make a specific and informed decision regarding his or her health care. The adequacy of the attending physician’s explanation in the consent process is judged by the “reasonable patient” standard — that is, what a reasonable person in the particular patient’s position would have expected to hear from his or her physician before consenting. This standard of informed consent is the product of two well-known Supreme Court of Canada decisions: *Hopp v. Lepp*14 and *Reibl v. Hughes*15. It should be reiterated that the Canadian standard is an objective one, based on the expectations of the recipient of the care as opposed to those of the attending physician. The law in Canada is to be contrasted with the law in the United Kingdom (and in some U.S. states) where the attending physician has the duty to inform the patient of only those risks of which the average, reasonable and prudent physician in the circumstances would inform the patient.16

As elaborated by the courts, risks that should be disclosed to the patient include risks of minor injuries that occur frequently and risks of serious injury or death, however remote. Hence, the materiality of a risk is influenced not only by the frequency of the possible risk but also by its seriousness should it occur.

In regard to alternatives to the proposed treatment, there is no obligation to discuss what might be considered unconventional or unavailable therapy, but patients should be advised about other viable and accepted alternatives and why the proposed treatment has been recommended instead.

Also, the authorization should be specific to the procedure actually performed and the patient should have the opportunity to ask the attending physician questions and to receive understandable answers.

The notion of informed consent to treatment also means that with regard to an innovative or experimental procedure (particularly non-therapeutic research), even greater care must be taken to fully disclose all known risks and anticipated results of the procedure. In such circumstances, the law requires an even higher quality of consent from the patient and standard of disclosure by the attending physician. For instance, it is the widely-held view that if the treatment is experimental, the physician’s exercise of therapeutic privilege is generally inappropriate and no information about the treatment may be hidden from the patient on the grounds that disclosure would result in the patient’s undue worry or anxiety.17

C. Exceptions to the Rule of Consent to Treatment

There are only a few limited exceptions to the general rule that all treatment requires the patient’s consent. One exception occurs where there is a life- or serious health-threatening situation requiring immediate treatment and where consent is either impractical or impossible to obtain. As this medico-legal emergency doctrine is defined in the Hospital Management Regulation,18 prescribed consents in writing need not be obtained where the delay caused by obtaining the consent would “endanger life, limb or vital organ”. In such circumstances, the surgeon, physician, dentist or administrator who would otherwise require the patient’s written consent must sign a statement confirming his or her opinion that a medico-legal emergency exists. Generally, medico-legal emergencies only arise when there is an imminent and serious danger to the patient and it is necessary to proceed immediately with the proposed treatment. The administrative convenience of either the attending health care professional or hospital is not a relevant consideration.

Another arguable exception to the general rule of “no consent, no treatment” is what has been called therapeutic privilege. In invoking this privilege, it has been said that the attending physician need not fully inform the patient where, in the physician’s professional opinion and because of emotional factors, the patient is unable to cope with all pre-treatment
explanations. Instead of the usual informed consent standard, the physician exercising the privilege may withhold or generalize information that would otherwise be given. It must be stressed, however, that therapeutic privilege is not clearly accepted in Canadian law. Indeed, it was recently rejected by the Ontario Court (General Division) in Meyer Estate v. Rogers. If it does exist, it is an extremely limited exception, to be exercised by the attending physician with the greatest discretion and only where clearly justified professionally in the clinical circumstances.

D. Special Cases of Consent

Special questions are raised by the consents to treatment of prisoners, involuntary psychiatric patients and minors. Also, special issues arise with consents relating to donations of tissue, organs, sterilization, artificial reproduction and clinical trials, to name a few. Some of these special cases draw on other requirements at common law and in statutes, but the general principles noted above for obtaining a valid consent remain.

E. Importance of Hospital Policies and Procedures on Consent

It is worth reiterating that the hospital and the attending physician must always distinguish between the process and the form of obtaining consent. There is no magic in the form itself; rather, the quality of the dialogue between the patient and the attending physician and the patient's ultimate understanding of the proposed procedure are determinative. Obviously, the quality of a particular patient's consent to treatment will depend not only on the attending physician and the consent forms used, but also on the quality and degree of staff compliance with the hospital's consent policies and procedures.

F. Principles for Drafting Consent Forms

In light of the foregoing, from a legal standpoint, consent forms should be drafted with the following principles in mind:

1. Unless accompanied by a detailed physician's note in the patient's record or long form consent, avoid short form and blanket consents that are generally worded and which purport to authorize all tests deemed appropriate by the attending physician in the circumstances.

2. Include on the form the full name, address and hospital and health insurance identification numbers of the patient, a description of the partner's medical condition, the name of the attending physician, the name, description and form of the proposed surgical operation, diagnostic test or medical treatment, and the names and brief descriptions of reasonable alternatives.

3. Use simple language, setting out the required information precisely and in understandable form (avoiding legalese and medical terminology, where possible). If the patient cannot understand English, an interpreter should be used and this fact clearly indicated on the form.

4. Particularly when the patient will be under anaesthesia, the form should authorize the attending physician in advance to use his or her judgment regarding predictable extensions of the procedure or operation or should unforeseen conditions arise during the procedure or operation. However, it must be stressed that such authorization means only that the attending physician should only proceed, without express consent, when something additional or alternative is immediately necessary or vital to the health or life of the patient, and not merely as a matter of convenience.

5. A clause should be inserted giving the attending physician the right to use associates, assistants and designates, which is particularly important on hospitals where health care providers work as a team and in a university teaching hospital, where delegation is common. From the patient's perspective, the clause should not be open-ended, but instead should restrict delegation to those chosen by the attending physician or surgeon.

6. A separate form, or at least separate clauses, should be used for the consent to the use of anaesthetics. This consent should refer to the type of anaesthetic intended and its administration by a particular anaesthetist, if known. Again, there is some debate among legal commentators over whether an additional consent is required. However, it is submitted that it is better to include this consent, if only to put the patient, attending physician and anaesthetist on notice of the separate medical risks and legal liabilities involved.

7. If the procedure is experimental or still in the investigative stage, this should be clearly stated on the form.
8. The form should include a clause stating that the attending physician has not given any guarantee of the results that may be obtained.

9. There should be a statement that the patient has received and understood all explanations, has had a chance to ask questions and has received understandable answers.

10. The form should be signed by the patient (or appropriate substitute consent giver, when required) and witnessed (not always a legal requirement, but prudent practice). Ideally, it should be signed as soon after the pre-treatment discussion as possible, always giving the patient or substitute consent giver ample time to consider what he or she is signing.

11. The date and time of the consent should be clearly marked on the form in the event that allegations are raised that the form was signed after the procedure was performed or after the patient had been medicated so that he or she was not mentally capable of giving consent.

12. There should be a signature and acknowledgment by the attending physician. While, presumably for reasons of administrative convenience and the self-interest of its members, the Canadian Protective Association does not recommend this requirement, in this writer's view, it is to be preferred, as it usefully draws attention to the attending physician's legal obligations.

13. It should be remembered that, unless otherwise required by law, many clauses and terms in so-called standard forms may be varied to reflect the individual nature, style and patient care policies of each particular hospital. Also, from a practical perspective, much of the detail in such forms might be omitted as a business decision made by the hospital with the knowledge of the legal risks that such omission entails.

14. Finally, the lay-out of the forms is almost as important as their content. Indeed, much imagination and skill are required to devise a simple format that accommodates the needs of both the hospital and the patient.

G. **Bill 109, an Act Respecting Consent to Treatment**

As already noted, this Bill was introduced (together with companion Bills 74 and 108) in the Ontario Legislature this past Spring. While a thorough review of this Bill is beyond the scope of this article, three points should be mentioned.

1. **Informed Refusal**

Section 5(2) of the Bill attempts to summarize the common law on “informed consent”. Nowhere in the Bill is reference made to the possible corollary of “informed refusal”. The question of whether, as a matter of law, a patient's refusal must be informed remains open and the Bill might seek to clarify this matter.

The Ministry's news release of May 27th quotes the Honourable Frances Lankin, Minister of Health, as stating that “This Act affirms the right of all Ontarians to be fully informed when deciding to accept or refuse a health service”. Put another way, the question left unanswered by the Bill is whether the patient also has, or ought to have, a legal obligation to be fully informed.

In *Malette v. Shulman*, the Ontario Court of Appeal stated that “It is unnecessary to determine in this case whether there is a doctrine of informed refusal”. However, in *obiter dicta*, the court seems to suggest that the right is not conditioned on an understanding of the risks of refusing care. Indeed, the trial judge is quoted by the court (with neither approval nor disapproval) as saying that “The right to refuse treatment is not premised on an understanding of the risks of refusal”. In light of this case, it would appear that a signed declaration (such as a Jehovah’s Witness card) is sufficient to withhold treatment from a person in need of life- or health-saving treatment.

However, it is submitted that a fair and principled extension of the law of informed consent requires that the patient know the nature and consequences of a refusal of treatment and that this requirement of “informed refusal” can be implemented in a manner consistent with the protection of religious freedoms under the Charter. Also, in its Booklet on Consent, the Canadian Medical Protective Association suggests that the refusal of care should be “informed”, in keeping with the underlying premise of the law of informed consent. Moreover, this approach is endorsed by Rozovsky L.E. and F.A., in *The Canadian Law of Consent to Treatment*, and evidently has been adopted by some American courts.

2. **Therapeutic Privileges**

Section 22(1) of the Bill attempts to
3. Protections for Health-Care Practitioners

Section 24[2] of the Bill is intended to protect the health-care practitioner who refrains from administering treatment to a person because of his or her refusal. It provides that such a health-care practitioner is "not liable for failure to administer the treatment". This would appear to be limited to liability from civil suit. Obviously, this is not sufficient protection to health-care practitioners, who may face disciplinary proceedings and criminal prosecution in difficult cases (even though this risk is more theoretical than real).

Either in this section of the Bill or in a section dealing with discipline in the proposed legislation under the Health Professions Legislation Review, a broader provision might be added to protect physicians and other health-care practitioners from disciplinary proceedings (such as a provision similar to that in section 6[1] of Bill 8, Mr. Sterling's Private Members' Bill on living wills32). Also, the Ontario government might seek to collaborate with the federal government to amend the Criminal Code along the lines proposed in Bill C-351 (also a Private Members' Bill).33

Conclusion

The law on consent to medical treatment and the use of consent forms is indeed complicated and this makes Bill 109 an ambitious legal drafting endeavour. Some aspects of the proposed legislation represent welcome clarification of the law; however, in its present form, several questions remain. Unfortunately, codifying, in a flexible and practical way, the existing common law and legislation on this ever-developing area is a difficult (perhaps even impossible) task. No doubt hospital administrators, health care professionals and their legal advisors will follow the Bill's progress and look forward to the start of public hearings on it (together with Bills 74 and 108) this Winter.

Notes


3. Sharpe, supra n. 1 at p. 83.


5. Rozovsky and Rozovsky, supra n. 1 at p. 1.

6. Or even a computer entry, pursuant to sections 1[1] and 33 of Reg. 518/88, as amended.

7. CMPA Booklet, supra n. 1 at p. 9.


10. Rozovsky and Rozovsky, supra n. 1 at p. 62.

11. CMPA Booklet, supra n. 1 at pp. 11-12.

12. It should be noted that some provinces already have legislation on this point — for example, Nova Scotia (see the Medical Consent Act, S.N.S. 1989 c. 279) and Quebec (see An Act respecting the Public Curator and amending the Civil Code and other legislative provisions).

13. CMPA Booklet, supra n. 1 at 9.


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...there was also a major problem of sexual deviancy in this case, although it had not previously involved serious aggression.

The apparent truism that childhood abuse/neglect (to the extent that they may have been relevant to these cases) may provide the basis for future violent behaviour is by no means clear cut. Balton et al., (1977), found that abused children were less likely to commit aggressive crimes.

The motivations underlying deviant sexual behaviour have been categorized by Groth (1979). Although neither of the two cases involved sexuality, there is a rough parallel with Groth's "power typology" in which the dominant factor involves control of the victim and the need for mastery. The sexual component in both cases involved excitement as well as fear and an intent to possess sexually. Presumably, both cases involved a combination of excitement and fear; the extent to which sexual gratification may have been involved in the actual killings is questionable. Whether similar fantasies or urges, perhaps combined with better resistance or restraint, are anything but a great rarity is uncertain. These highly unusual cases do not seem to fit into any current taxonomy of classification of sexual offenders.

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17. CMPA Booklet, supra n. 1 at pp. 19-20.

18. Section 25(5) and (6), O. Reg. 518/88, as amended.


21. Sharpe, supra n. 1 at p. 89.

22. For another general discussion of this subject, see Sharpe, supra n. 1 at pp. 85-90.

23. See CMPA Booklet, supra n. 1 at p. 23 and Sharpe, supra n. 1 at p. 87.

24. See CMPA Booklet, supra n. 1 at p. 27.

25. Supra n. 2 at p. 336.


27. Ibid. at p. 326.

28. Supra n. 1 at p. 21.

29. Supra n. 1 at p. 11; citing Truman v Thomas, 611 P. 2d 902 (Kal. 1980).

30. Supra n. 20.

31. Supra n. 19 and n. 20.

32. This bill received second reading on April 11, 1991.

33. This bill received first reading on June 19, 1991.

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in the advance directive (either through written instruction in a living will or oral instruction to his/her proxy) how he or she makes decisions.


22. Risks associated with legally requiring respect for advance directives are noted in, for example: Davidson K.W., Hackler, C., Caradine, D., and McCord, R., "Physicians' Attitudes on Advance Directives"; Fisher R.H., and Meslin, "Should living wills be legalized?";