Legislating for an Informed Consent to Medical Treatment by Competent Adults

Introduction

Unlike its American counterpart, the Canadian medical profession has shown admirable restraint in the face of rapid development in medical law. Rather than agitate for legislative restriction of legal obligations, the Canadian medical profession has been content to trust to judicial development of the legal obligations of the practice of medicine. The American "malpractice crisis" of the mid-1970's induced a flurry of legislative initiatives to clarify the legal obligations of medical personnel. On the matter of a patient's consent to medical treatment, some states enacted standards of information that had already been established in the courts, while others adopted different standards.

In Ontario the Interministerial Committee on Medical Consent, which was originally commissioned in 1978 to study consent by minors and sexual sterilization of the mentally incompetent, published an omnibus report on general issues of consent to medical treatment. It is expected that legislation will be introduced in some form sometime in 1981 or 1982. The United States has already had some experience with codification of the principles of consent. In view of the interest in this issue shown in Ontario, and in view of recent judicial developments in the area of informed consent in Canada, it is appropriate to examine the earlier American effort. The work of the Ontario Interministerial Committee is not the first provincial incursion into the domain of consent to medical treatment. However, it is the first omnibus attempt. Previous reports and existing legislation focus on special cases of consent, particularly consent by those under the age of majority.

---

2 In 1979 a discussion paper was issued, followed by recommendations and draft legislation: see Options on Medical Consent (September, 1979) and Options on Medical Consent — Part 2 (December, 1979), both published by the Ministry of Health in Ontario.
3 Legislation was not introduced earlier because the Government was under significant pressure not to proceed with the recommended proposals. This pressure came primarily from anti-abortion groups concerned with the provisions regarding consent to health care by minors, and with sexual sterilization of mental incompetents.
4 See, e.g., provisions concerning consent to treatment by minors in [La] Loi sur la protection de la santé publique, L.R.Q., c. P-35; Art. 20 of the Civil
I. Legislating for informed consent: the American response

American legislation concerning informed consent ranges from the relatively simple to the remarkably complex. The legislation purports to speak to the various issues raised by the judicial doctrine of informed consent. Primary among these is the standard of disclosure of risks. Not surprisingly, the overwhelming legislative trend is to establish a professional standard of disclosure. One suspects that in most cases the intention of the legislature was to ensure that disclosure of material risks not become a part of the law of the jurisdiction. In at least two states, the legislation reverses a judicially imposed standard requiring disclosure of material risks. In one state the legislative standard imposes a broader duty of disclosure on treating physicians than had the court imposed professional disclosure rule.

6 See Ludlam, Informed Consent (1978), 41; Anna, supra, note 1. Seidelson concluded in 1976 that approximately half of the United States had a judicially imposed full disclosure standard, and it seems likely that the primary impetus behind the legislation is a desire to forestall or deny such a standard: see Medical Malpractice: Informed Consent Cases in Full Disclosure Jurisdictions (1976) 14 Duquesne L. Rev. 309. See also Ludlam, supra, 42, who suggests conflicting court decisions as an additional motivating factor.


The common thrust of the legislation is to define the information necessary to an informed consent. If the decreed information is disclosed, the consent of the patient is then presumed, if the legislation follows an evidentiary model. If the legislation follows a cause of action model, no action will lie in the face of a valid consent. The standard of disclosure varies. Statutory adoption of a professional standard of disclosure is most common. New York requires the disclosure that "a reasonable medical practitioner under similar circumstances" would provide. Other states have gone further, providing legislative validation of a locality rule in the context of informed consent. Thus the Delaware Code defines an informed consent as one where the information given was that "customarily given to patients ... by other licensed health care providers with similar training and/or experience in the same or similar health care communities". Adoption of a locality rule seems particularly inappropriate in the context of informed consent. It was partly because a professional standard of disclosure is often a fiction that some courts preferred an objective or full disclosure standard. Other state legislation leaves the standard of disclosure unclear, perhaps inadvertently. For example, Ohio requires disclosure of "the nature and purpose of the procedure or procedures, and what the procedures are expected to accomplish, together with the reasonably known risks". Presumably, risks are reasonably known if other physicians in the same circumstances know or ought to know of them. If risks are reasonably known, is there discretion

---

9 This classification is adopted by Ludlam, supra, note 5, 42. For an example of an evidentiary model, see Iowa Code Ann. § 147.137 (Supp. 1977): "A consent in writing to any medical or surgical procedure or course of procedures in patient care which meets the requirements of this section shall create a presumption that informed consent was given."

10 For an example of a cause of action model, see Delaware Code Ann. Tit. 18 § 6852 (1976): "No recovery of damages based upon a lack of informed consent shall be allowed in any action for malpractice unless ... ."

11 See Ludlam, supra, note 5, 47; Annas, supra, note 1.


14 E.g., Canterbury v. Spence, supra, note 6.

to withhold information, regardless of the actions of one’s colleagues? Or does “reasonably known” refer to the risks it is reasonable for the patient to know, and provide scope for withholding information in accordance with the practice of one’s colleagues?

Prior to the legislation, the standard of disclosure in Ohio was an objective or full disclosure standard. Originally, the legislation required disclosure of an enumerated series of risks only; specifically death, brain damage, quadriplegia, paraplegia, loss of function of an organ or limb, and disfiguring scars. This list was a clear retreat from the position taken by Ohio courts. The 1977 amended version of the Ohio legislation is equivocal.

The legislative provisions of at least two states, Pennsylvania and Washington, codify judicially imposed standards requiring disclosure of material risks. The Pennsylvania Health Care Services Malpractice Act requires disclosure of “those risks and alternatives to treatment or diagnosis that a reasonable patient would consider material to the decision whether or not to undergo treatment or diagnosis.” Washington legislation is in virtually the same language.

The legislative models in two other American states are of interest. Colorado originally required disclosure of the statistical degree of risk within two per cent. The statistical degree of risk was to be determined either by reference to “a recognized medical publication” or by reference to the physician’s personal experience based on a “substantial number of the same or similar procedures.” A risk of less than two per cent presumably did not need to be disclosed. Only risk of death and risk of “serious injury” required disclosure, but “serious injury” was left undefined. Apparently, the

---

18 Supra, note 16.
22 § 13-20-302(2).
23 Annas, supra, note 1, 12. Case law requires disclosure of a serious risk the incidence of which is less than two per cent. See Canterbury v. Spence, supra, note 6, in which it was held that a one per cent risk of possibility of paralysis from laminectomy must be disclosed.
legislation was found to be unworkable and within one year it was repealed. It has not been replaced.\textsuperscript{24}

The most ambitious legislative provision concerning information disclosure for medical consent is that in Texas.\textsuperscript{25} Legislation adopted in 1977 established a nine-member Texas Medical Disclosure Panel. Six members of the panel must be licensed to practice medicine in the state and the others must be licensed to practice law.\textsuperscript{26} The legislative mandate of the Panel is to establish two lists of medical procedures, those requiring disclosure of risks and those not requiring disclosure. The Panel is to establish the degree of disclosure required.\textsuperscript{27} These lists are to be reviewed annually.\textsuperscript{28} The Panel has not yet published a list either of procedures requiring disclosure, or of those requiring no disclosure. In 1978 it published a tentative list for discussion only, including a tentative standard form of consent. The legislation establishes a rebuttable presumption of consent to medical care if disclosure has been made in accordance with the list of risks and hazards provided by the Panel, or if there has been no disclosure but the procedure is on the Panel's non-disclosure list. Where the procedure is on neither list the standard "otherwise provided by law" applies.\textsuperscript{29} Here the legislation states:

In a suit ... based on the failure of the physician or health care provider to disclose or adequately to disclose the risks and hazards involved ..., the only theory on which recovery may be obtained is that of negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent.\textsuperscript{30} This is an ambiguous standard, requiring proof that the failure to disclose material risks\textsuperscript{31} was negligent. Reference to negligence leaves open the defence that one's medical colleagues did not disclose the risk in question. Alternatively, a court could find that it is negligent to fail to disclose all material risks. Prior to the legislation, the standard imposed by Texas courts was a professional standard of disclosure.\textsuperscript{32} The Texas proposal is surely an ambitious one, but

\begin{footnotesize}
\begin{enumerate}
\item Ludlam, supra, note 5, 49.
\item 1977 Texas Sess. Law Serv. Ch. 817 §§ 6.03-6.07.
\item § 6.03(c).
\item § 6.04(b).
\item § 6.04(d).
\item § 6.07(2)(b).
\item § 6.02 (emphasis added).
\item The statutory language refers to risks that "could have influenced a reasonable person".
\item Wilson v. Scott 412 S.W. 2d 299 (Tex. 1967).
\end{enumerate}
\end{footnotesize}
it seems a Herculean task. It is best understood as legislative approval of a professional standard of disclosure, combined with a legislative directive designed to ensure that a reasoned, professional consensus exists.

Definition of the standard of disclosure is at the centre of all American legislation concerning informed consent to medical treatment. In addition, many state statutes deal with the other issues raised by the judicial doctrine of informed consent. A few focus on the debate over the appropriate cause of action, preferring negligence. Texas is the most explicit. Any action based on failure to disclose risks associated with the procedure may be based in negligence only. Failure to disclose the nature of the procedure itself appears to fall outside the language of the statute. It is not clear, therefore, that the language of the statute successfully lays the issue to rest. Presumably, in most states the controversy continues, except to the extent settled by state courts.

Many statutes codify the common law exceptions or defences to an action based on failure to obtain an informed consent. Whether drafted as exceptions or as defences, the list generally includes emergency, therapeutic privilege or a provision that the risk in question was a universally understood risk. Certain statutes also make reference to a clear indication of waiver of disclosure by the patient. Delaware legislation incorporates all of these:

---

83 Mr Caroll Gregory of the Texas Department of Health assured the author that the task assigned to the Texas Medical Disclosure Panel has not been abandoned as unworkable. The proposed lists, published in the Texas Register for discussion-purposes only, make no mention of the statistical incidence of risk. For example the “Procedures Requiring Full Disclosure” list includes an abdominal hysterectomy (total) under the heading “Female genital system treatments and procedures”. The listed risks are (i) difficulty in passing urine, (ii) injury to bladder, (iii) sterility, (iv) injury to the tube between the kidney and the bladder. Disclosure of sterility is specifically required. Included on the list of “Procedures Requiring No Disclosure” is a ligation of the fallopian tubes. This procedure apparently requires the disclosure of no risks, neither the risk of regeneration of the fallopian tubes, nor of sterility.

84 See 1977 Texas Sess. Law. Serv. ch. 817 § 6.03-6.07 and Arizona, Ariz. Rev. Stat. § 12-562(b) (1976). No “medical malpractice” action may be based on assault and battery. “Medical malpractice” is defined as including claims based on the failure to obtain an informed consent. (§ 12-561(2)). See Ludlam, supra, note 5, 47.

35 As for example in Schweizer v. Central Hospital (1974) 6 O.R. (2d) 606 (H.C.) where plaintiff consented to a procedure of fusion of the joint of his toe and a spinal fusion was performed.
(a) No recovery of damages based upon a lack of informed consent shall be allowed in any action for malpractice unless:

(1) The injury alleged involved a nonemergency treatment, procedure or surgery;

(...)

(b) In any action for malpractice, in addition to other defenses provided by law, it shall be a defense ... that:

(1) A person of ordinary intelligence and awareness in a position similar to that of the injured party could reasonably be expected to appreciate and comprehend hazards inherent in such treatment;

(2) The injured party assured the health care provider he or she would undergo the treatment regardless of the risk involved or that he or she did not want to be given the information or any part thereof to which he or she could otherwise be entitled; or

(3) It was reasonable for the health care provider to limit the extent of his or her disclosures [sic] of the risks of the treatment, procedure or surgery to the injured party because further disclosure could be expected to affect, adversely and substantially, the injured party's condition, or the outcome of the treatment, procedure or surgery.36

The language of the statute as to the emergency exception is less precise than the common law defence it codifies. Most statutes waive the requirement of consent where the injury arises out of emergency treatment. At common law, it is not the emergency nature of the treatment alone that justifies proceeding without consent. It is emergency in combination with lack of ability in the patient to comprehend treatment and its implications, and the unavailability of a substitute consent. To expect a court to include these additional criteria in defining emergency treatment is to ask the court to correct sloppy drafting. Language used by other states more clearly codifies the common law rule.37

Therapeutic privilege, codified at subsection three of the Delaware Code, is available at common law even in those states that have a judicially imposed standard requiring disclosure of material


37 See, e.g., Washington Rev. Code Ann. § 7.70.050(4) (1976): "If a recognized health care emergency exists and the patient is not legally competent to give an informed consent and/or a person legally authorized to consent on behalf of the patient is not readily available, his consent to required treatment will be implied". See also Kentucky Rev. Stat. § 304.40.320(3) (Supp. 1976); Pa Stat. Ann. Tit. 40 § 1301.103; Nev. Rev. Stat. § 41A.120 (1975).
The codifying language is useful, however, in emphasizing that disclosure must "substantially" affect the patient’s condition. Several of the statutes codify the principles of causation applicable where informed consent is at issue. The New York State provision is typical.

It must also be established that a reasonably prudent person in the patient’s position would not have undergone the treatment or diagnosis if he had been duly informed and that the lack of informed consent is a proximate cause of the injury... Even states that judge disclosure according to a professional standard impose the more onerous objective standard on injured patients. Alaska is apparently the only state that balances a professional standard of disclosure with a subjective evaluation of the patient’s decision had he been properly informed. The plaintiff must establish that "but for that failure [to disclose] the claimant would not have consented." Most state statutes do not deal specifically with the issue of causation, preferring only to define the cause of action. In the absence of a specific provision, common law principles govern.

Finally, several of the statutes deal specifically with the issue of substituted consent, often summarily. Maine provides that health care must not be given without the informed consent of "the patient or the patient’s spouse, parent, guardian, nearest relative or other person authorized to give consent for the patient". Ohio refers to a non-exhaustive list of situations requiring substituted consent, specifically incompetence, infancy and the effects of drugs or alcohol, and provides for consent by a person "who has legal authority to consent ... in such circumstance."

Is the American effort to codify the principles of informed consent a useful one? For those state legislatures that want to avoid or repudiate a court imposed standard of disclosure legislation is the only means available. Often, however, more care should have gone

---

into the drafting of the legislation. The Texas attempt to list the procedures requiring disclosure and the risks that must be disclosed is perhaps the most interesting, although it is open to any medical association to undertake the same task without legislative direction. Such a list, if one could be compiled, would be of persuasive value even in jurisdictions having a standard requiring disclosure of material risks.

II. Legislation for Ontario?

Do the Canadian provinces need similar legislation? The purview of the Interministerial Report in Ontario is much broader than the general principles of consent to medical treatment. It extends to several special cases of consent, including incompetents and children, and to special procedures such as sterilization and psychosurgery. Perhaps with regard to these special cases legislation is necessary, but the concern here is with the general case of consent to treatment only.

The proposed legislation in Ontario is well drafted, in fact better drafted than the legislation in any of the American states. Had it been adopted immediately upon release of the final report of the Interministerial Committee in December, 1979, it would have significantly changed the law of Ontario concerning informed consent to medical treatment. In particular, the draft legislation rejected a professional standard of disclosure of risks in favour of disclosure of material risks or those “that a reasonable person would require in order to make a decision in the circumstances.” In the interim, however, judicial development has significantly overtaken the draft proposal, particularly as to general principles of consent. The Supreme Court of Canada recently determined that negligence is usually the appropriate form of action where a failure to obtain consent is concerned, and the Court has applied an objective standard to both the physician’s disclosure and to the issue of causation.

The draft legislation improves on any of its American counterparts in several respects. The definition of an informed consent requires disclosure of the information “that a reasonable person would require in order to make a decision in the circumstances”.

---

44 “Draft Health Care Services Consent Act” published in Options on Medical Consent — Part 2, supra, note 2: see s. 4.
46 S. 4.
thus imposing an objective standard of disclosure. The draft proposal is concerned with the nature of the consent, not the cause of action where consent is not obtained. Therefore, the proposal deals neither with the appropriate cause of action, nor with the issue of causation, leaving these to be determined by the courts. The legislation is useful in specifying that a competent adult may refuse consent to treatment even where life is threatened, and in establishing a clear hierarchy of those who are legally authorized to give a substituted consent. It is important to note that with regard to consent by competent adult persons the draft proposal makes little change in the common law. The draft proposal defines the information necessary for an informed consent and provides a definition of the competency necessary to consent. A person is competent if “able to understand and appreciate the nature and consequences of the health care service and able to understand and appreciate the consequences of giving or withholding the consent.”

Several exceptions or defences are specified. Consent is unnecessary in an emergency. Here the draft proposal adopts the language of the better American models. Where a person is unconscious or incompetent to consent to health care and a delay would result in “imminent and serious danger” to life, limb or a vital organ, medical assistance may be given. Section 14 provides an additional defence, though one that is less successfully conceived. No action for damages shall be brought

(a) on the basis of a lack of valid consent for providing a health care service in accordance with a consent that the (defendant) had reasonable cause to believe was a valid consent . . . .

This section was presumably included to provide a defence of good faith where the consenting individual was reasonably believed to be of the age of consent, as defined by the proposal, or competent, when not so in fact. However, it is drafted with sufficient breadth as to empty the material disclosure rule in section 4 of

---

47 S. 8(1): “A proposed recipient of a health care service who is mentally competent to consent to the provision of the health care service has the authority to give or withhold consent to the provision of the health care service.” While this is probably the case at common law, the point is not perfectly clear.

48 S. 1(1)(c).

49 Before the decisions of the Supreme Court of Canada in Hopp v. Lepp and Reibl v. Hughes, a professional standard of disclosure was most often applied: see Rodgers Magnet, Lepp v. Hopp and Reibl v. Hughes: Recent Developments in the Doctrine of Informed Consent to Medical Treatment (1980) 14 C.C.L.T. 61.

50 S. 3.
all content. If the physician had reasonable cause to believe that consent was given, but disclosure consonant with the information a “reasonable person would require” had not been made, is he excused from liability? Worse, can the physician show he had reasonable cause to believe the consent was valid because he had disclosed information in accordance with the practice of his colleagues? This admittedly aberrant reading of section 14 is exacerbated as this section speaks of the validity of a consent. While competence is required for a valid consent, disclosure of information also affects its validity. A consent based on insufficient information is an invalid one.51

The strong points of the draft proposal include the definition of competency, imposition of an objective standard of disclosure, clarification of the right to refuse treatment and of those able to provide substituted consent. The criteria to be considered by the person giving a substitute consent are also of great interest. Both the best interests and the wishes of the patient are to be considered.52 Special provisions with regard to those under the age of majority, for institutionalized patients and for special procedures are outside the scope of this short note.

The proposal makes no reference to causation, nor to cause of action, presumably leaving these to the courts. More significantly, the proposal makes no reference to therapeutic privilege or specific waiver. These existing common law defences do not fall within the section 14 defence of reasonable belief that consent was valid. Rather, they are situations where a valid consent is absent, but with justification. Furthermore, the language of the proposal defining a valid consent is such that the defence of waiver or therapeutic privilege may be excluded entirely. Whether inadvertent or intended, exclusion of such defences is inappropriate. Their exclusion may be a by-product of the fact that the report was originally envisioned to treat the issue of sexual sterilization of the mentally retarded but grew to encompass the entire field of medical consent.

Conclusion

Is legislation necessary, or appropriate, on the general question of consent to medical treatment? In my opinion it is not. The impetus to legislation in the United States was the rapid escalation in insurance premiums, combined with withdrawal of insurance

51 This is the result of reading ss. 2 and 3 in conjunction with s. 14.
52 S. 12.
corporations from the medical malpractice market. Legislation concerning informed consent was part of a general package designed to reduce the number and size of claims. It is suggested that neither the American models on informed consent, nor the Ontario model, succeed in this aim. Lack of consent is still grounds for an action in damages, as it should be. Nor is the legislative definition any more precise than the judicial one. In either case a physician must determine what to disclose in a given situation. It is this task that is difficult, and here the legislation is of little or no assistance. Finally there has been no demand for legislation from the medical profession. Where legislation merely ossifies an existing situation, provides no saving of cost and is the subject of neither public nor specialized demand, legal development is best left to the judiciary.

S. Rodgers Magnet*

*Of the Faculty of Law, University of Ottawa.