Informed Consent: From Material Risks to Material Information

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Informed Consent: From Material Risks to Material Information

There has been a decisive break with the "health professional knows best" attitude that dominated most of the last century. Dentists and other health care professionals today live in a world where priority is given to the autonomy of the patient. What might be called the "informational asymmetry" between the expert health care professional and the lay patient poses a challenge for the full exercise of a patient's autonomy. The legal and ethical duty of a dentist to obtain informed consent levels the playing field by ensuring that the patient understands the most important aspects of treatment. The mere fact that a patient sits in the patient's chair is a far cry from informed consent in today's legal environment.

This article will discuss some of the key principles that emerge from the legislation, cases, and disciplinary decisions around informed consent. Many of the cases involve other types of health professionals, particularly doctors, but the same principles are applicable to dentists.

While the law of informed consent is full of intricacies and challenges, some of the key points about informed consent discussed in this article include:

1. Informed consent is a process: It involves dialogue between dentist and patient. Consent should be obtained before the commencement of treatment and renewed throughout the course of treatment.

2. "Informed" includes all material information, not just material risks: As case law on informed consent has developed, courts have expanded the scope of what a patient is entitled to know. The courts take a patient-centric view of what a reasonable patient would like to know, including alternative procedures, risks, and side effects.

3. Understanding and appreciation: A patient has the capacity to consent when he or she understands the information relevant to making a decision about the treatment and appreciates the reasonably foreseeable consequences of a decision or lack of a decision. Particular care must be had with young children and with adult patients who have cognitive disability.

4. Encourage questions: Questioning by patients allows a doctor to appreciate what is important for the patient's specific circumstances and lifestyle. Questioning by a patient is often the best evidence of the patient's understanding.

5. Delegation: A dentist may delegate discussions about informed consent but must be very careful in doing so. The dentist remains responsible for any failure in obtaining informed consent and must ensure that the delegate is competent.

6. Consent forms: Consent forms can be an important tool to allow patients time to reflect on a proposed course of treatment. But a signature on a consent form is only one piece of the puzzle. A signed consent form is evidence of dialogue about informed consent but is not the consent itself.

7. Lists of risks and side effects: These lists can be useful tools in ensuring that a patient is aware of the material and serious risks and side effects of a treatment. Caution must be used with these lists, as it is easy to omit an item and they must be updated in light of new research.

8. Detailed charting and documentation: Detailed, contemporaneous notes of discussions with a patient about consent are the best evidence that meaningful dialogue occurred. The maxim that "if it wasn't charted, it didn't happen" is a slight exaggeration but it remains an important rule of thumb.

9. Standardized practice: Courts are prepared to accept evidence of a dentist's invariable practice regarding discussions of consent as evidence that a discussion occurred in a particular context. Sticking to a standardized practice, while remaining responsive to the particular concerns of an individual patient, is essential.

INFORMED CONSENT IS A LEGAL AND ETHICAL DUTY OF DENTISTS

Outside of emergency situations, where a patient's consent to treatment may be presumed, informed consent is required before a health care practitioner can initiate any treatment in Ontario.

Informed consent is both a legal and an ethical duty for dentists. Dentists owe a duty of care to their patients to ensure that they provide informed consent to a treatment. If the patient is not properly informed of the nature of the treatment, its risks, and alternative procedures, a dentist may face civil liability in a case where the procedure leads to complications.

Informed consent is also an ethical duty for dentists. Failure to obtain consent for a procedure for which consent is required is professional misconduct under s. 2(7) of the *Professional Misconduct Regulation*, O. Reg. 853/93 under the *Dentistry Act, 1991*, S.O. 1991, c. 24. Failure to obtain consent could result in a finding of professional misconduct.

As a practical matter, a substantial number of patient complaints about lack of informed consent arise in the context of billing disputes. Ensuring that the patient is fully informed about the cost of dental treatment ahead of time can place a treatment in financial context and thus reinforce the patient's understanding of how serious it is.

WHAT IS INFORMED CONSENT?

The modern law of informed consent in the health care context can be traced to the Supreme Court of Canada's 1980 decisions in *Hopp v Lepp* and *Reibl v Hughes*. In *Hopp v Lepp*, the court unanimously recognized the need for consent by a patient to treatment to be properly informed:

> [the doctrine of "informed consent"] reflects the fact that although there is, generally, prior consent by a patient to proposed surgery or therapy, this does not immunize a surgeon or physician from liability for battery or for negligence if he has failed in a duty to disclose risks of the surgery or treatment, known or which should be known to him, and which are unknown to the patient. The underlying principle is the right of a patient to decide what, if anything, should be done with his body: see *Parmley v. Parmley and Yule* at pp. 645-46. (I leave aside any question of emergency or of mental incompetency and, also, situations where the operation or treatment performed or given is different from that to which the patient consented.) It follows, therefore, that a patient's consent, whether to surgery or to therapy, will give protection to his surgeon or physician only if the patient has been sufficiently informed to enable him to make a choice whether or not to submit to the surgery or therapy. The issue of informed consent is at bottom a question whether there is a duty of disclosure, a duty by the surgeon or physician to provide information and, if so, the extent or scope of the duty.

The court further elaborated on the nature of the duty of a health professional to ensure that a patient was sufficiently informed as follows:

> [the health professional] 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.

The health professional's duty to answer questions and disclose risks is a duty to do these things in the manner of a reasonable practitioner. In other words, if a dentist answers a question incorrectly or is unaware of a material risk, it is no defence to rely on that ignorance if a reasonably competent dentist would be aware of these matters. The law of informed consent thus imports a duty of continuing education on dentists and other health practitioners. A patient is entitled to reasonable answers to his or her questions. Moreover, a dentist should pay particular heed to what these questions say about a patient's circumstances or interests.

MATERIAL RISKS MUST BE DISCLOSED

One of the more common issues that arises with respect to informed consent relates to the non-disclosure of risks which then materialize. A patient who was not warned of the existence of these risks may justifiably feel wronged when they result from an operation.

On the other hand, there is a danger in dentists focusing exclusively on the risks of a treatment in discussions with a patient. The patient may lack the expertise to place these matters in context and may be scared away from a beneficial treatment in the face of a long list of risks and side effects. Indeed, the Ontario Court of Appeal recognized in 1981 in *Videto v Kennedy* that the emotional condition of the patient and his or her reluctance to undergo the recommended treatment may in some cases justify the dentist in withholding or generalizing information as to which he or she would otherwise be required to be more specific. Withholding information in these circumstances should only be done after careful consideration and documentation of the basis for the decision.

The balance struck by the courts has been that a dentist must disclose material risks and special risks. The materiality of a risk is measured both by the gravity of the outcome and the frequency of its occurrence. A relatively minor risk should be disclosed if there is a substantial likelihood of it occurring. Not every remote possibility needs to be disclosed, but where the consequences are serious, such as permanent disability or death, the risk should be disclosed even where the probability of occurrence is low.

The discussion of risks should focus on the specific treatment being proposed. In the case of surgery, it is not necessary to disclose all the attendant risks of surgery in general, such as those of anesthetic or of infection, subject to the requirement that particularly grave risks should be disclosed.

FROM MATERIAL RISKS TO MATERIAL INFORMATION

The earlier cases such as *Reibl v Hughes* placed heavy emphasis on the importance of health care practitioners disclosing risks and the consequences of non-disclosure of such risks. Courts rapidly expanded the notion of informed consent to go beyond the disclosure of risks and the answering of specific questions to a broader duty to provide all material information to a patient relevant to a decision about treatment.

This broader concept of informed consent is reflected in the meaning of informed consent that has been set out by statute in Ontario. Under s. 11 of the *Health Care Consent Act*, 1996, SO 1996, c 2, Sch A, consent is informed where a dentist informs of the patient of:

- the nature of the treatment
- the expected benefits of the treatment
- the material risks of the treatment
- the material side effects of the treatment
- alternative courses of action
- the likely consequences of not having the treatment
- the answers to the patient's questions about the treatment.

Besides the disclosure of material risks, discussion of alternative treatments is one of the most important aspects of informed consent. Allowing the patient to understand the options, including the consequences of inaction, is essential for the patient to make an informed decision about the treatment. Ideally, a dentist would discuss the key features of the alternative treatment(s), including material risks and benefits.

It is only necessary to discuss true alternatives to the proposed course of treatment. Thus, in one case, a surgeon failed to discuss a non-surgical means of removing kidney stones. However, the patient had specifically expressed a desire to avoid recurrence of the pain and this result would not be achieved by the non-surgical option. The court held that there was no need for the doctor to disclose an alternative treatment that was not responsive to the patient's desires. That said, dentists may wish to err on the side of caution in discussing alternative treatments to avoid the risk that a court will find after the fact that a near alternative should have been disclosed.

Similarly, where a health care professional prefers one form of treatment to another that is more commonly accepted, he or she should disclose that fact and explain his or her position on the advantages of the preferred treatment. It is not acceptable to simply go ahead with the preferred treatment without informing the patient of the issue.

At a more extreme level, a health care practitioner must inform a patient where a proposed treatment is untested, experimental, or faces skepticism from the broader community of practitioners.

INFORMED CONSENT IS PATIENT-CENTRIC

As the Supreme Court observed in *Reibl v Hughes*:

> The patient may have expressed certain concerns to the doctor and the latter is obliged to meet them in a reasonable way. What the doctor knows or should know that the particular patient deems relevant to a decision whether to undergo prescribed treatment goes equally to his duty of disclosure as do the material risks recognized as a matter of required medical knowledge.

In this and other passages, the Court recognized that informed consent is to be assessed from the perspective of the patient. In other words, the question is not what a reasonable health care professional would disclose, but what a reasonable person in the patient's position would want to know about the procedure. One consequence of this is that a court will look beyond the professional standards of the dentistry profession when determining what information should have been disclosed to a patient. This includes documents such as the RCDSO's *Practice Advisory: Informed Consent Issues Including Communication with Minors and with Other Patients Who May Be Incapable of Providing Consent* (August 2007). Such standards are an important factor to be taken into consideration but they are not determinative of civil liability.

Another implication of the patient-centric approach to informed consent is that the health professional need not even be aware of personal circumstances that would cause a patient to forego or postpone treatment for a patient to recover damages. The Ontario Court of Appeal made this point in *Lue v St. Michael's Hospital*. The patient was left with permanent paralysis in his right hand, arm, and leg following a surgery to remove a brain aneurysm. The patient maintained that he was not informed of the risk of such paralysis and that if he had been informed, he would have delayed the surgery for several months, by which point he would have become eligible for long-term disability insurance benefits. The trial judge rejected the patient's claim on the basis that the doctor had not been informed of these economic circumstances but the Court of Appeal disagreed with the trial judge on this point. When a doctor fails to disclose a material risk and the patient, acting reasonably, would have chosen a different course of action had the risk been disclosed, the patient is entitled to damages regardless of whether the doctor was aware of the circumstances. Ultimately, however, the Court of Appeal denied the patient's claim because he did not prove that he would in fact have postponed the surgery. Liability for a breach of the duty to warn by a dentist in a situation where a patient could prove that he or she would have taken a different course of action (whether

postponing the treatment or foregoing it altogether) would be calculated so as to compensate the patient for any loss or injury that would not have arisen if he or she had been properly warned.

The patient-centric nature of informed consent means that the courts will consider the specific circumstances of a given patient. This is because certain risks will be more salient for some patients than others. Younger patients or patients whose appearance is important for their profession may be more concerned about scarring or other disfiguration. A sole parent with several dependents may be particularly averse to any risk of serious disability. The importance of timing may also play a role, as in the case of *Reibl v Hughes* itself, where the patient would have been entitled to a lifetime pension if the surgery were carried out 18 months later.

The shift to a patient-centric understanding of informed consent does not mean that the "patient is always right." Dentists must respect a patient's bodily autonomy but this does not give patients a right to receive medically unnecessary treatment. Where a dentist believes there is no reason for a requested treatment, he or she may justifiably decline to provide it.

CAPACITY TO CONSENT

One of the most difficult areas relating to informed consent occurs with respect to questions of capacity. Under s. 4(1) of the *Health Care Consent Act*, a patient has the capacity to consent when he or she understands the information relevant to making a decision about the treatment and appreciates the reasonably foreseeable consequences of a decision or lack of a decision. The ability to "understand" and "appreciate" requires certain cognitive functions, including memory, reasoning and decision-making ability. In most cases, a dentist may presume that a patient has the capacity to consent. Two special cases that call for attention are minors and adults with cognitive disabilities.

In Ontario, there is no fixed age of capacity to consent for medical treatment. Whether or not a minor is able to consent turns on a case-by-case determination by the health care practitioner involved. The RCDSO's *Practice Advisory* on informed consent recommends a presumption that minors under the age of 12 are unable to consent, while minors above the age of 16 are able to consent. The more difficult cases will involve minors between 12 and 16. In these cases, a dentist should hold a discussion with the patient about the proposed treatment and elicit questions from the patient that might assist the dentist in gauging the patient's understanding and appreciation of the treatment. Careful, contemporaneous notes should always be made of the content of these discussions and of their outcome. If a minor lacks the capacity to consent, a parent or guardian must consent to the treatment on his or her behalf.

In cases involving minors, it is essential to draw a clear distinction between the customer (usually a parent or guardian who is paying for the services) and the patient (the minor). A dentist's obligations with respect to his or her patients are not changed simply because a third party is paying the bills. In such a scenario, the dentist must preserve patient confidentiality unless and until the patient consents to information being shared with a parent or guardian.

Where there is reason to doubt the capacity of an adult patient to consent to a treatment, a dentist should discuss the proposed treatment with the patient and attempt to gauge the patient's appreciation and understanding of the treatment. If the dentist is of the view that the patient lacks the capacity to consent, the dentist should inform the patient of this and of the patient's right to appeal this decision to the Consent and Capacity Board. More information on the issue of capacity to consent can be found in the RCDSO's *Practice Advisory*.

Another special case involves language barriers. Where the dentist and patient do not speak the same language, the dentist must ensure that a translator is involved so that the patient is fully informed. A family member or friend may be able to play this role, but dentists should be sensitive to any pressure being placed on the patient by other family members.

Regardless of whether there are any communication difficulties, dentists should resist the urge to use jargon and should try to speak to patients in plain English. As one court put it "the language used by the doctor should be such that the patient can easily understand it. The utilization of medical terms replete with Latin words does not satisfy this requirement." In one case, a health professional disclosed the risk of a stroke to his patient but the patient did not understand what a stroke was or that it was a serious matter. The court decided that greater explanation was needed of the causes and effects of such a serious risk.

While assessments of a patient's understanding may be challenging in a clinical setting, there are objective steps that a dentist can take to increase the likelihood that he or she will be understood by the patient. The trial judge

in *Lue v St. Michael's Hospital* set out a number of objective criteria for courts to consider when determining whether a patient properly understood a proposed treatment and most of these factors can be addressed by proper procedures, as set out by Eleanor Cronk in her 2001 article on informed consent.

1. Whether the patient asked any questions. A failure to ask appropriate questions may indicate the patient is overwhelmed and uncomprehending. As a corollary, the comments or questions that the patient does raise may also reveal comprehension of the material risks.

2. Whether diagrams or other visual aids are relevant. Depending on the intellectual abilities of the patient, pictorial depictions may be part of the process.

3. Whether the patient can restate what the physician has communicated. At some point after the disclosure, can the patient describe, in his or her own terms, the procedure and risks which are about to unfold.

4. Whether the patient has asked for a second opinion. Patients are understandably reluctant to be perceived as doubting the advice of the doctor by suggesting a second opinion. But when the "organ of our humanity" is involved, the doctor should consider raising it as a possibility and explain to the patient how that course of action could be implemented.

5. Whether any information is put in writing. For example, does the patient have access to brochures which describe the generic condition with usual questions and answers? Did the dentist write a note or letter to the patient? Did the dentist make a note in the patient's chart? Is there a protocol in writing for the physician to follow and was it followed?

6. Whether the time spent with the patient is realistic in terms of enabling the patient to comprehend the nature of the treatment and to have this message reinforced? Is the patient afforded an opportunity to ask questions?

7. Whether the patient is dependent on family members for assistance in decision-making or whether the treatment, or lack thereof could result in impaired cognitive abilities. In either case, involvement of the family is not a courtesy, it is a necessity. If others are involved, whether their recollection of events coincides with the doctor's will be an important consideration.

8. Whether the patient or family express spontaneous surprise when the event, described in advance as a material risk, unfolds. A court may look to this as circumstantial evidence of the disclosure that was made beforehand.

WHO PROVIDES THE INFORMATION?

It has been settled in the case law for some time that a health professional does not personally need to inform the patient of all material facts relating to a proposed treatment. These discussions can be delegated to a competent colleague, such as a dental hygienist. These discussions can also be carried out by multiple practitioners, so that different aspects of a treatment are discussed by different members of a team or practice. In some cases, courts have even accepted that information provided by a health professional who was a friend of the patient was sufficient. The cases recognize that the main consideration is that the patient actually be informed.

The availability of a wealth of medical information on the internet raises an interesting question for the law of informed consent, namely, what weight should be given to the fact that a patient has conducted his or her own research online? Even if a health professional neglects entirely to inform the patient of the relevant information, the patient might in fact be equally or even better informed than patients with more diligent dentists by virtue of internet research. This issue was considered by the Saskatchewan Court of Appeal in the case of *Prevost v Ali.* The court held that the significance of information from a non-medical source would depend on the circumstances of a given case, but held on the facts of that case that the information obtained by the plaintiff from the internet was not sufficient to constitute informed consent. The patient had a grade 8 education and there was no evidence before the court as to the quality of the internet research he had conducted.

CONSENT FORMS

There are a number of tools available to assist dentists in ensuring that patients are well-informed and empowered to make decisions about their treatment.

Consent forms present a serious danger in that they can create a false sense of security. A patient's signature on a consent form is only as good as the information that the patient actually receives in the course of the consultation with the dentists. As a leading text, *The Canadian Law of Consent to Treatment,* 3rd ed (Markham: LexisNexis, 2003) puts it:

> ...consent is a 'process' and not a form. The fact that a person has signed a consent form does not necessarily mean that consent has been given, that it was informed, that the consent was valid, or that the procedure performed was the procedure for which consent was obtained. In considering whether there has been a valid consent, a court is required to examine all relevant circumstances, not just the written form.

This being said, consent forms can play an important role by focusing the patient's attention on the importance of consent. The ideal consent form would be tailored to the specific procedure at issue and would address the gravity of the procedure, the material risks, side effects, alternative treatments, and the consequences of inaction. Any list of risks should not minimize the likelihood of such risks occurring.

CAUSATION AS A LIMIT ON CIVIL LIABILITY

Where a patient can show that his or her dentist failed to provide sufficient information about some form of treatment, the next question for a court is whether the patient is entitled to any damages. The benchmark for this analysis is what a reasonable person in the patient's position would have done, had he or she been properly informed of the material facts.

Note that it is not enough for the patient to say that he or she had a subjective fear or aversion to a particular risk or side effect of the treatment. Rather, the patient must show that a *reasonable* person would have decided on a different course of treatment had he or she been properly informed about the treatment. The advantage of this approach is that a patient is not allowed to rely on idiosyncratic fears after the fact to suggest what would have occurred. Discussions around informed consent must center on what a reasonable person in the patient's position would base a decision about the treatment on. This rule – first formulated by the Supreme Court in *Reibl v Hughes* and was later confirmed by it in *Arndt v Smith* – provides some measure of protection to dentists and other health professionals.

It is important to bear in mind the situation of the individual patient when evaluating what is reasonable in a given case. For example, the loss of an eye as a result of the non-disclosure of this outcome as a material risk might bring about the loss of a job for which good eyesight is essential. The fact that the patient works in a job where eyesight is important gives particular weight to the non-disclosure of this risk. The court in *Reibl v Hughes* emphasized that a patient's particular concerns must be reasonably based. A plaintiff's idiosyncratic fears or desires will not be allowed to shape the contours of a dentist's liability.

There must be a causal connection between the failure of the dentist to disclose material information and the harm suffered by the plaintiff and the plaintiff must be able to prove this causal link. This requires that the plaintiff must be able to show that a reasonable person in his or her position would have acted differently and so avoided the loss. Timing will be significant in some cases, such as *Reibl v Hughes* itself, where a delay of 18 months would have solidified the plaintiff's financial outlook. However, the plaintiff must do more than simply show that a delay in the treatment would have occurred if proper disclosure had been made. This is particularly so where the treatment itself was competently performed but complications arose nonetheless. In a number of decisions, including by the Ontario Court of Appeal in *Felde v Vein and Laser Medical Centre*, the courts have held that plaintiffs may not rely on an inference that, if the surgery had been postponed, chance would have shown them more favour.

DISCLOSURE OF PERSONAL FACTS BY HEALTH PROFESSIONALS

One interesting application of the causation principle has arisen in the case law with respect to a health care practitioner's duty to disclose matters relating to his or her own health. In *Halkyard Estate v Mathew*, the patient suffered complications from a hysterectomy and died. It emerged that the surgeon suffered from epilepsy, for which he was taking medication. There had been no seizure during the course of the operation and the patient's death was causally unrelated to the surgeon's

epilepsy. The plaintiff claimed that the surgeon had breached his duty of disclosure by failing to disclose the existence of the condition and that, if the matter had been disclosed, the surgery would not have gone ahead. The Alberta Court of Appeal held that a doctor has no duty of disclosure with respect to his or her own health issues where these are unrelated to harm suffered by a patient.

In another case involving disclosure by a health care practitioner, it was decided that a health professional was under no obligation to disclose his lack of experience where he was qualified to render the treatment in question. Obviously, a patient might be nervous to learn that a dentist had never carried out a procedure before but all dentists have to start somewhere. An alternative approach to this question that has been taken by some courts is to say that a reasonable person would consent to a treatment by a properly qualified health professional regardless of their level of experience and so no losses flow from a failure to disclose a lack of experience.

SUMMARY

The paradigm shift initiated by the Supreme Court in *Hopp v Lepp* and *Reibl v Hughes* 35 years ago has had a profound impact on the relationship between dentists and their patients. The patient-centric approach taken by courts and regulators requires health professionals to be skilled not only at delivering treatment but also at consulting with patients and ensuring that they are empowered to make fully informed decisions about their health. This imperative requires dentists to exercise sound judgment in what can be difficult clinical settings.

While the boundaries of what must be communicated to patients continue to evolve, patients themselves are able to access vast quantities of health care information through digital means that could not have been imagined in 1980. As the nature of the dentist-patient relationship and the legal concept of informed consent continue to evolve, the foundation of dentist-patient dialogue will endure as a touchstone of sound practice.

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