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INFORMED CONSENT AND PATIENT COMPREHENSION: THE LAW AND THE EVIDENCE

*Sarah Burningham, Christen Rachul & Timothy Caulfield**

Introduction

Few areas of health law attract as much attention as informed consent. In Canada, several well-known Supreme Court cases,[1] and, in some provinces, health care consent laws,[2] provide that physicians must obtain the informed consent of patients prior to providing medical treatment. While the basic parameters of informed consent law are clear, confusion remains about the extent of the duty of physicians to ensure that patients understand the information provided. The need for patient comprehension is self-evident: providing patients with information facilitates decision making and promotes autonomy only if patients are able to understand that information. However, it may be challenging for physicians in practice to meet legal or ethical obliga-

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* Sarah Burningham, Health Law Institute, University of Alberta, Edmonton, AB; Christen Rachul, School of Linguistics and Language Studies, Carleton University, Ottawa, ON; Timothy Caulfield, Health Law Institute, Faculty of Law and School of Public Health, University of Alberta, Edmonton AB. We would like to thank SafetyNET, Alberta Innovates-Health Solutions, CIHR, and the Women's and Children's Health Research Institute, University of Alberta for funding support as well as our colleagues at the Health Law Institute, University of Alberta for research support. We would also like to thank Dr Cheryl Mack, Department of Anesthesiology and Pain Medicine, University of Alberta, for discussions that inspired this paper.

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[1] *Reibl v Hughes*, [1980] 2 SCR 880, 114 DLR (3d) 1 [*Reibl*]; *Hopp v Lepp*, [1980] 2 SCR 192, 112 DLR (3d) 67.

[2] Health Care Consent Act, 1996, SO 1996, c 2, Schedule A; Health Care (Consent) and Care Facility (Admission) Act, RSBC 1996, c 181; Consent to Treatment and Health Care Directives Act, RSPEI 1988, c C-17.2.

tions to ensure patient comprehension, as evidence suggests that many patients do not understand complex medical information or risk information. Reviewing relevant jurisprudence and professional ethics, we examine the nature of this obligation, followed by a discussion of empirical evidence relating to patient comprehension. Based on this review, we suggest that there is a disconnect between what the law expects and what patients experience during the informed consent process.

I. The Law

The breadth of what should be provided as part of the consent process is significant and, in general, includes anything a reasonable person in the patient's position would want to know.[3] Over the years, judicial interpretation of consent law has consistently expanded the parameters of the disclosure obligation to include, for example, even relatively remote risks.[4] As a result, meeting this significant legal obligation can, from a practical perspective, be a challenge.[5]

But merely providing patients with relevant information is not the only challenging component of the informed consent process. Canadian law clearly imposes some responsibility on physicians to ensure patients understand what they have been told. In *Reibl v Hughes,* and later in *Ciarlariello v Schacter*,[6] the Supreme Court appeared to place a burden on physicians to ensure patients understood the information provided to them. In *Ciarlariello v Schacter,* Cory J for the Court held:

> Prior to *Reibl v. Hughes*, there was some doubt as to whether the doctor had the duty to ensure that he was understood. However, Laskin C.J. made it quite clear in that case that it was incumbent on the doctor to make sure that he was understood, particularly

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[3] *Reibl*, *supra* note 1.

[4] See e.g. *Malinowski v Schneider*, 2012 ABCA 125, 71 Alta LR (5th) 34 (finding that "a rare but potentially catastrophic consequence" ought to have been disclosed to the patient); *White v Turner* (1981), 31 OR (2d) 773, 120 DLR (3d) 269 (HCJ) (finding that, "[w]here an operation is elective, …even minimal risks must be disclosed to patients").

[5] Colleen M Flood, "Conundrums in Causation and Informed Medical Consent" (2000) 23 Advocates' Q 217 at 220; Ellen I Picard & Gerald B Robertson, *Legal Liability of Doctors and Hospitals in Canada*, 4th ed (Toronto: Thomson Canada Limited, 2007) at 135-41.

[6] [1993] 2 SCR 119, 100 DLR (4th) 609.

> where it appears that the patient had some difficulty with the language spoken by the doctor.
>
> Indeed, it is appropriate that the burden should be placed on the doctor to show that the patient comprehended the explanation and instructions given.[7]

The burden described by Cory J in *Ciarlariello* has been criticized by both academics and judges. In their influential text, *Legal Liability of Doctors and Hospitals in Canada*,[8] Picard and Robertson suggest that the burden in *Ciarlariello* is "too onerous and impractica[l]."[9] Rather, they propose, physicians should "take reasonable steps to ensure that the patient understands" what he or she is told.[10]

Lower courts have similarly criticized *Ciarlariello*.[11] For example, in *Byciuk v Hollingsworth*, the Alberta Court of Queen's Bench stated:

> That expansive burden [in *Ciarlariello*] has been criticized as unrealistic. See Ellen I. Picard and Gerald B. Robertson Legal Liabilities of Doctors and Hospitals in Canada (3d edition) Toronto: Carswell, 1996 at 137.
>
> I agree that the burden described by Cory, J. is too onerous. I prefer the proposal of the above authors. It is sufficient if the physician takes reasonable steps to ascertain whether the patient understood the message being conveyed.[12]

Lower courts have interpreted *Ciarlariello* narrowly, holding that physicians have a duty to take reasonable steps to ensure that patients understand what they are told if patients are older, are distressed, or have trouble with lan-

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[7] *Ibid* at paras 54-55.

[8] Picard & Robertson, *supra* note 5.

[9] *Ibid* at 161. See also Kevin Williams, "Comprehending Disclosure: Must Patients Understand the Risks They Run?" (2000) 4 Medical Law International 97 at 101-02; Margaret A Somerville, "Structuring the Issues in Informed Consent" (1981) 26:4 McGill LJ 740 at 780.

[10] Picard & Robertson, *supra* note 5 at 161.

[11] *Byciuk v Hollingsworth,* 2004 ABQB 370, 358 AR 312 at paras 32-33 [*Byciuk*]; *Sadlowski v Yeung*, 2008 BCSC 456, 57 CCLT (3d) 305 at para 104 [*Sadlowski*]; *Loffler v Cosman*, 2010 ABQB 177 at paras 206-09 [*Loffler*].

[12] *Byciuk, ibid* at paras 32-33.

guage.[13] But, it should be noted that the courts have, when asked, consistently confirmed that this obligation does in fact reside with the physicians.[14] While the lengths to which physicians must go to discharge the duty continues to be debated, there is little doubt that physicians do indeed have such a duty. The responsibility is confirmed by relevant professional guidelines. In particular, the Canadian Medical Association's Code of Ethics provides that physicians must "[m]ake every reasonable effort to communicate with…patients in such a way that information exchanged is understood."[15]

The main point is clear: physicians have an ethical and legal obligation to take reasonable steps, at minimum, to ensure patients understand the information provided to them. The duty rests with physicians and what "reasonable steps" will discharge the duty "depend[s] on the particular circumstances of each case."[16]

II. The Evidence about Patient Understanding

The practicality of this obligation, and how it can best be operationalized, must be considered, given the mounting social science evidence that suggests that many patients do not understand the information they are given during the informed consent process.[17] In particular, patients have trouble understanding probability data, as they often do not understand information in-

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[13] *Martin v Findlay*, 2008 ABCA 161 at para 38; *Byciuk*, *ibid* at paras 31-34; *Sadlowski*, *supra* note 11; *Loffler*, *supra* note 11 at para 208; Kenneth G Evans, "Consent: A Guide for Canadian Physicians", 4th ed, (The Canadian Medical Protective Association, 2006) online: CMPA <www.cmpa-acpm.ca>.

[14] *Reibl*, *supra* note 1; *Gilberds v Sobey*, 2011 ABQB 491 at para 95.

[15] Canadian Medical Association, *Code of Ethics* (Ottawa: Canadian Medical Association, 2004), online: Canadian Medical Association <http://policybase.cma.ca/dbtw-wpd/PolicyPDF/PD04-06.pdf>.

[16] Picard & Robertson, *supra* note 5 at 161; *Byciuk*, *supra* note 11 at para 33.

[17] BM Stanley, DJ Walters & GJ Maddern, "Informed Consent: How Much is Enough?" (1998) 68 Australian & New Zealand Journal of Surgery 788; Allison E Crepeau et al, "Prospective Evaluation of Patient Comprehension of Informed Consent" (2011) 93:19 Journal of Bone & Joint Surgery American Volume e114; Jürgen JW Mulsow, T Martin Feeley & Sean Tierney, "Beyond Consent: Improving Understanding in Surgical Patients" (2012) 203:1 American Journal of Surgery 112; Jeff Whittle et al, "Understanding of the Benefits of Coronary Revascularization Procedures Among Patients Who Are Offered Such Procedures" (2007) 154 American Heart Journal 662; Sonu Pathak et al, "Consent for Gynaecological Procedure: What Do Women Understand and Remember?" (2013) 287 Archives of Gynecology & Obstetrics 59.

volving numbers.[18] Additionally, evidence suggests that the "framing" of numerical information can influence decision making.[19]

The fact that patients have difficulty understanding risk information and other medical information suggests that physicians may not easily discharge their duty regarding patient comprehension. For example, teaching patients to understand probability data may take an extensive time commitment beyond what can be reasonably expected of physicians. Even with education, patients may still have trouble understanding some concepts.

The matter is made more complex by two additional factors. First, physicians have trouble recognizing that patients do not understand information or have not received sufficient information necessary to make a decision.[20] Second, patients struggle to identify their own misunderstanding. Patients overwhelmingly believe they are well informed and understand the information provided to them.[21] How can physicians meet their obligation respecting patient comprehension when neither physician nor patient can properly identify misunderstanding? Additionally, patient misunderstanding cannot be corrected simply by encouraging patients to ask questions, because

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[18] Lisa M Schwartz et al, "The Role of Numeracy in Understanding the Benefit of Screening Mammography" (1997) 127:11 Annals of Internal Medicine 966; R Fuller, N Dudley & J Blacktop, "How Informed is Consent? Understanding of Pictorial and Verbal Probability Information by Medical Inpatients" (2002) 78:923 Postgraduate Medical Journal 543; Richard Fuller, Nigel Dudley & Jon Blacktop, "Risk Communication and Older People: Understanding of Probability and Risk Information by Inpatients Aged 75 Years and Older" (2001) 30:6 Age & Aging 473; Isaac M Lipkus, Greg Samsa & Barbara K Rimer, "General Performance on a Numeracy Scale among Highly Educated Samples" (2001) 21:1 Medical Decision Making 37.

[19] Schwartz et al, *ibid*; Judith Covey, "A Meta-analysis of the Effects of Presenting Treatment Benefits in Different Formats" (2007) 27:5 Medical Decision Making 638.

[20] Marko Jukic et al, "Physicians Overestimate Patient's Knowledge of the Process of Informed Consent: A Cross-Sectional Study" (2011) 8:1 Medicinski Glasnik 39; M Gattellari et al, "Misunderstanding in Cancer Patients: Why Shoot the Messenger?" (1999) 10 Annals of Oncology 39.

[21] Mulsow, Feeley & Tierney, *supra* note 17; PJD Dawes, L O'Keefe & S Adcock, "Informed Consent: The Assessment of Two Structured Interview Approaches Compared to the Current Approach" (1992) 106 Journal of Laryngology & Otology 420.

they "may not know enough to enable them to frame specific or even general questions."[22]

Clearly, a gap exists between what the law expects and what actually occurs during the informed consent process. Indeed, the evidence regarding patient comprehension may undermine bedrock principles of informed consent. Informed consent is based on the notion that medical decisions are properly within the realm of patient autonomy. Patients should be provided with sufficient information to enable them to make informed decisions. Courts often assume that patients understand this information.[23] A review of the evidence challenges this assumption.

Conclusion

Informed consent, built on a long and well-developed body of jurisprudence and bioethics literature, is a foundational cornerstone of health law in Canada. For this reason, we do not advocate in this article revisiting the theoretical principles underlying informed consent law. Rather, we suggest that, given the practical problems associated with implementation, physicians, lawyers, and policy makers consider methods and approaches to ensure informed consent works in practice.

For example, there are several interventions identified in the academic literature that may improve patient comprehension. The evidence suggests that interventions—such as leaflets, multimedia, or testing—are generally helpful, especially in improving patients' knowledge of risks.[24] Additionally, providing physicians with communication skills training may improve patient understanding.[25] Such interventions may help physicians meet their ethical and legal obligations.

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[22] Picard & Robertson, *supra* note 5 at 164-65.

[23] Williams, *supra* note 9.

[24] Yael Schenker et al, "Interventions to Improve Patient Comprehension in Informed Consent for Medical and Surgical Procedures: A Systematic Review" (2011) 31:1 Medical Decision Making 151; Mulsow, Feeley & Tierney, *supra* note 17. *Contra* H Brown et al, "Are Patient Information Leaflets Contributing to Informed Consent for Cataract Surgery?" (2004) 30 Journal of Medical Ethics 218.

[25] Pranitha Naini et al, "Evaluation of a Method to Improve the Consent Process: Improved Data Retention with Stagnant Comprehension" (2013) 28 Journal of Cancer Education 38.