Informed consent from the legal, medical and patient perspectives: the need for mutual comprehension

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La norme juridique du consentement libre et éclairé aux soins constitue un élément important de la mise en valeur de l'autonomie du patient et de sa participation plus active à la prise de décision clinique. Pourtant, on note des distorsions importantes entre la théorie juridique du consentement aux soins et sa réception par les acteurs visés par la norme, soit principalement les professionnels de la santé et les patients. La loi tel qu'actuellement définie ne semble pas offrir de lignes directrices suffisantes pour en assurer la pleine application, posant ainsi des difficultés sur le plan de son effectivité. Ce faisant, nous soumettons que des solutions pratiques et efficaces doivent être apportées afin de permettre au consentement aux soins d'atteindre sa pleine effectivité en matière de reconnaissance de l'autonomie des patients. Notamment, la norme juridique du consentement aux soins pourrait être bonifiée par la reconnaissance du modèle de la prise de décision partagée, des incitatifs législatifs pourraient être envisagés pour favoriser l'utilisation d'outils d'aide à la décision par les professionnels de la santé avec leurs patients, et des efforts supplémentaires devraient être considérés afin d'améliorer l'offre éducative en matière de communication interpersonnelle pour les médecins.

Informed consent is an essential part of patient engagement in medical decision-making, and serves to improve patient adherence to treatment. However, distortions exist between the theory of informed consent and its reception by healthcare professionals and patients; the existant law does not provide satisfactory guidelines for its application. Practical and effective applications of the right to informed consent are urgently needed. Possible solutions could involve: adoption of shared decision-making as a model, legislation to encourage use of accredited patient decision aids, and incentives to increase physician training in communication skills.

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INTRODUCTION

Recent years have seen a growing interest in patient engagement in medical decision making. Patient engagement has been shown to improve health outcomes[1] as well as reduce costs[2]. At the very foundation of patient engagement lies the concept of informed consent, legally and ethically required in order to fully respect patient autonomy. Informed consent is a hybrid concept informed by both the medical and the legal fields, and lies at the centre of many medicolegal debates[3]. Although obtaining informed consent is legally mandatory, its application is fraught with difficulty[4].

In this analysis, we first present the significant flaws that have become evident in the clinical application of informed consent as well as in its legal enforcement, not least because doctors and lawyers interpret and observe it differently. We show that

1. Judith H. Hibbard and J. Greene, « What the evidence shows about patient activation: better health outcomes and care experiences; fewer data on costs » (2013) 32:2 Health Affairs 207.
2. Judith H. Hibbard, J. Greene and V. Overton, « Patients with lower activation associated with higher costs; delivery systems should know their patients' "scores" » (2013) 32:2 Health Affairs 216.
3. Lorene E. Rozovsky, The Canadian Law of Consent to Treatment, 3rd ed, Markham, LexisNexis Canada, 2003.
4. D. E. Hall, A. V. Prochazka and A. S. Fink, « Informed consent for clinical treatment » (2012) 184:5 CMAJ 533; Sarah Burningham, Christen Rachul and Timothy Caulfield, « Informed Consent and Patient Comprehension: The Law and the Evidence » (2013) 7:1 McGill Journal of Law and Health 123.

when it is effective, however, informed consent is associated with several positive outcomes, including reduced risk of litigation[5] and enhanced patient adherence to treatment[6]. We raise questions about patients' perceptions of the informed consent process and their role in it, and we conclude by proposing some solutions to the problems, and call for further investigation.

1. The challenge

Enforcing the requirement of informed consent alone does not ensure full patient autonomy. A necessary corollary to the requirement to obtain consent is the requirement to inform, i.e. help patients identify decision points and provide them with valid and reliable information on the treatment to which they are asked to consent as well as possible alternatives. Patients continue to express the desire to be informed about the issues relevant to medical decision making, and more and more wish to be involved in it[7]. Yet it would appear that they do not receive as much information, quantitative or qualitative, as informed consent would require. For instance, a large study has revealed that primary care physicians and surgeons had disclosed complete information on procedure, alternatives and risks in only 3.1% of the 3552 medical decisions analysed[8].

In spite of difficulties, informed consent has shown to be a powerful tool for promoting quality improvement, patient safety and risk management in health care[9]. Feeling informed and properly involved in the decisional process may enhance adherence to treatments[10], and may be essential to patient satisfaction with health care[11]. It is not surprising, then that it appears to be of particular importance in the

5. Evelyn M. Tenenbaum, « Using Informed Consent to Reduce Preventable Medical Errors » (2012) 21 Annals of Health Law 11.
6. L. R. Martin et al., « The challenge of patient adherence » (2005) 1:3 Therapeutics and Clinical Risk Management 189.
7. D. J. Mazur et al., « The role of doctor's opinion in shared decision making: what does shared decision making really mean when considering invasive medical procedures? » (2005) 8:2 Health Expectations 97; B. Chewning et al., « Patient preferences for shared decisions: a systematic review » (2012) 86:1 Patient Education and Counseling 9.
8. C. H. Braddock 3rd et al., « Informed decision making in outpatient practice: time to get back to basics » (1999) 282:24 JAMA 2313.
9. Tenenbaum, supra note 5.
10. Martin et al., supra note 6.
11. Richard Grol et al., « Patients in Europe evaluate general practice care: an international comparison » (2000) 50:460 The British Journal of General Practice 882; Angela Coulter and P. D. Cleary, « Patients' experiences with hospital care in five countries » (2001) 20:3 Health Affairs 244.

prevention of malpractice lawsuits. An Australian study, for instance, found that one in nine medical complaints concerned informed consent and most were related to risks not having been properly explained[12]. A Canadian study found that lower scores on communication and clinical decision-making in the national licensing exam were associated with more patient complaints to medical regulatory authorities being retained after investigation[13]. Levinson et al. found that physicians facing no malpractice claims were significantly more educating and orientating patients than those who had faced malpractice claims, and were better at soliciting patients' opinions and questions or verifying their understanding of the issues[14].

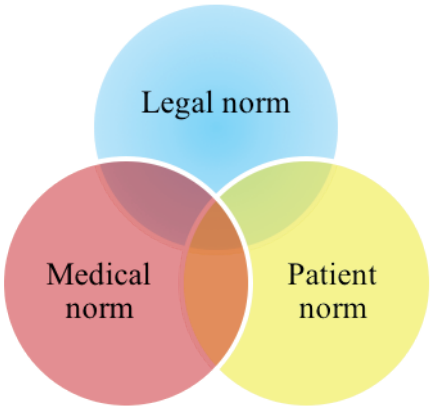
As the benefits of truly informed consent for both patients and healthcare professionals have been convincingly demonstrated, one wonders why its application has remained so chaotic, from the time it was first legally and medically recognized to the present day.

2. Mismatched norms

In practice, requiring informed consent involves many different actors who each have their own perceptions and understanding of what informed consent means and whether it has taken place. One concept that helps both explain the difficulties encountered in the practice of informed consent and suggests solutions is internormativity, an approach that requires examination of the point of intersection of patients' conceptions and those of the legal and medical fields. Internormativity may be defined as the acceptance or incorporation by one group of a norm (standard) derived from another group[15]. Besides, we here suggest that patients, as individuals, have their own expectations, values and preferences, and therefore carry individualized norms that must be taken into account when discussing informed consent. What this represents in the context of informed consent practice can be roughly summarized using a Venn diagram (Figure 1). Shared norms, in the case of informed consent, occupy small part of the actors' overall perceptions.

12. A. J. Gogos et al., « When informed consent goes poorly: a descriptive study of medical negligence claims and patient complaints » (2011) 195:6 Med J Aust 340.
13. R. Tamblyn et al., « Physician scores on a national clinical skills examination as predictors of complaints to medical regulatory authorities » (2007) 298:9 JAMA 993.
14. W. Levinson et al., « Physician-patient communication. The relationship with malpractice claims among primary care physicians and surgeons » (1997) 277:7 JAMA 553.
15. Guy Rocher, « Les "phénomènes d'internormativité" : faits et obstacles » in Jean-Guy Belley, dir, Le droit soluble. Contributions québéoises à l'étude de l'internormativité, Paris, LGDJ, 1996, p. 25.

Figure 1. Internormativity in the application of informed consent.



2.1. Legal norm

From a legal standpoint, informed consent may be viewed as a contract for medical services whereby a patient authorizes a healthcare professional to provide a treatment[16]. The law has generally considered the requirement of informed consent to be based on the fundamental right to autonomy and protection of the person's integrity. In practical terms, the boundaries of the practice of informed consent have evolved through civil liability jurisprudence, and in Canada have not significantly changed since 1980[17]. Generally speaking, a patient seeking damages for defective consent must demonstrate three elements: 1) that the healthcare professional committed a breach of his duty to disclose information (e.g. did not appropriately disclose risks or alternatives); 2) that the patient has suffered a loss or injury; and 3) that causality exists between the healthcare professional's fault or breach and the patient's loss. The fault is evaluated by asking what one reasonable patient, with the particular patient's characteristics, would have expected to know before giving his consent. As for causation, the question is "would one reasonable patient, in the particular patient's position, not have given his consent, had he been appropriately informed?" These assessments are known as the "reasonable patient standard", because they imply that the judge must "objectify" the complainant's consent[18].

16. Rozovsky, supra note 3.
17. Reibl c Hughes, [1980] 2 SCR 880.
18. Robert P. Kouri and Suzanne Philips-Nootens, L'intégrité de la personne et le consentement aux soins, 3rd ed, Cowansville, Éditions Yvon Blais, 2012.

Although the law describes informed consent as a process, the boundaries drawn by jurisprudence make it appear more like a sequence of technical requirements[19]. This is not a helpful guideline for the kind of open and real dialogue that is necessary to discovering what information is relevant for consent to be truly informed in a healthy patient-physician relationship[20].

The legal conception and application of the requirement of informed consent have thus fallen short in protecting patients' autonomy and integrity. In the following section, we explain further how the legal perspective on informed consent has generated norms that do not intersect with those that have evolved in the field of healthcare.

2.2. Medical norm

The Canadian Medical Protective Association (CMPA) refers to the Shorter Oxford English Dictionary's definition of consent ("the voluntary agreement to or acquiescence in what another person proposes or desires; agreement as to a course of action"), and posits that in medical contexts, informed consent relies upon the "basic accepted principle that 'every human being of adult years and of sound mind has the right to determine what shall be done with his or her own body'"[21]. It appears, however, that healthcare professionals find it particularly difficult to know the exact nature of their legal duty of information disclosure[22]. The law does not seem to recognize the uncertainty in medical knowledge itself[23], an uncertainty which makes it difficult for healthcare professionals be clear about what information should be disclosed to the patient, or how.

Moreover, healthcare professionals in general seem reluctant to set aside their own preferences and perceptions of patients' needs in order to achieve consent that is fully informed; they rarely fully understand how they should practise informed consent. Heywood et al. have looked at the practice of informed consent

19. R. Heywood, A. Macaskill et K. Williams, « Informed consent in hospital practice: health professionals' perspectives and legal reflections » (2010) 18:2 Medical Law Review 152; A. Maclean, « Autonomy, consent and persuasion » (2006) 13:4 European Journal of Health Law 321.
20. M. A. Jones, « Informed consent and other fairy tales » (1999) 7:2 Medical Law Review 103; Jay Katz, « Informed consent--must it remain a fairy tale? » (1994) 10 The Journal of Contemporary Health Law and Policy 69.
21. Kenneth G. Evans, Consent, A guide for Canadian physicians, 4th ed., Ottawa, Canadian Medical Protective Association, 2006.
22. M. M. Bismark et al., « Legal disputes over duties to disclose treatment risks to patients: a review of negligence claims and complaints in Australia » (2012) 9 PLoS Med e1001283.
23. Jay Katz, The Silent World of Doctor and Patient, Baltimore, The Johns Hopkins University Press, 2002.

in the UK[24]. Although the legal principles regarding informed consent in the UK somewhat differ from those in Canada, their article provides valuable insight into how the requirements of informed consent are viewed and applied by healthcare professionals. Their study reveals that the legal informed consent requirements are often perceived as highly bureaucratic by healthcare professionals, and that the extent of information disclosure is often determined by healthcare professionals on the basis of their perception of the patient's needs. Medical practice also seems to focus on disclosing risks at the expense of discussing benefits and alternatives, which may be explained, in part, as a response to the fear of litigation. The actual medical practice of informed consent is thus based on quite a different set of norms from those provided by the law.

2.3. Patient norm

We found little literature on the patient perspective on informed consent. This appears to confirm the general sense that informed consent is something that is done to patients – healthcare professionals sometimes even use the expression "consenting a patient"[25] – without them actually expressing what they know about it or expect from it. Nevertheless, we can make some remarks on the role played by patients in clinical decision making, a role which has implications for how they perceive informed consent. Evidence suggests, firstly, that patients may be reluctant to ask their healthcare professional questions[26] and that only 14% of patients would actually tell their physicians if they disagreed with their recommendations[27]. Secondly, studies show that patients are not able to accurately assess their own understanding of the information given to them in the encounter: in broad terms, feeling informed is not necessarily the same as being informed[28]. Studies in the US suggest that knowledge and understanding of medical information by patients are inadequate for informed consent[29]. These findings are of concern, especially when additional

24. Heywood, Macaskill et Williams, supra note 19.
25. Ibid.
26. J. S. Blumenthal-Barby, « 'That's the doctor's job': Overcoming patient reluctance to be involved in medical decision making » (2017) 100:1 Patient Education and Counseling 14.
27. J. R. Adams et al., « Communicating with physicians about medical decisions: a reluctance to disagree » (2012) 172:15 Archives of Internal Medicine 1184.
28. Karen R. Sepucha et al., « How does feeling informed relate to being informed? The DECISIONS survey » (2010) 30:5 Suppl Medical Decision Making 77S.
29. Angela Fagerlin et al., « Patients' knowledge about 9 common health conditions: the DECISIONS survey » (2010) 30:5 Suppl Medical Decision Making 35S; M. E. Falagas et al., « Informed consent: how much and what do patients understand? » (2009) 198:3 American Journal of Surgery 420.

data suggests that patients' understanding is assessed by physicians in less than 2% of medical decisions[30].

Informed consent is a concept that was developed by jurists but that is applied in practice and experienced on a daily basis by healthcare professionals and patients. It emerges from the differing perspectives we outline above that the norms applied by the law may not be relevant to the needs or practice of actors involved in shaping and applying informed consent. We will hereafter suggest a few solutions that could reflect a mutual understanding of informed consent.

3. Possible solutions

The failure of informed consent has been described as "a consequence of lawmakers having elaborated the parameters of the doctrine[31]." It seems clear that the time has come to redefine informed consent and change how it is applied in routine clinical context. Looking beyond purely legal solutions, we need to be cognizant that the practice of informed consent is internormative, i.e. it should not evolve without patients and the medical field being wholly involved in that change[32]. Jurisdictions elsewhere have attempted legal and policy solutions that have evolved out of a mutual understanding of informed consent, solutions which could be adapted to the Canadian reality.

One practical solution that has been advocated in the past decade is to adopt shared decision making between patients and physicians as the leading model of care[33], a model that could increase the internormative "space" to the benefit of all. Shared decision making has been defined as "an interpersonal, interdependent process in which the [healthcare professional] and the patient relate to and influence each other as they collaborate in making decisions about the patient's health care. Shared decision making is patient specific, and it relies on the medical evidence, the provider's clinical expertise, and the unique attributes of the patient[34]." The clinical practice model offered by shared decision making acknowledges the constant

30. Braddock et al., supra note 8.

31. J. L. Dolgin, « The legal development of the informed consent doctrine: past and present » (2010) 19:1 Camb Q Health Ethics 97, p 97.

32. Katz, supra note 23.

33. Jamie S. King et Ben W. Moulton, « Rethinking informed consent: the case for shared medical decision-making » (2006) 32:4 American Journal of Law & Medicine 429; Ben Moulton et al., « From informed consent to informed request: do we need a new gold standard? » (2013) 106 J R Soc Med 391; Ben Moulton et Jamie S. King, « Aligning ethics with medical decision-making: the quest for informed patient choice » (2010) 38:1 The Journal of Law, Medicine & Ethics 85.

34. France Legare et Holly O. Witteman, « Shared decision making: examining key elements and barriers to adoption into routine clinical practice » (2013) 32:2 Health Affairs 27, p 276.

dialogue that must take place between the patient and the healthcare professional, thus offering an exchange environment that is truly favourable to the patient's autonomy[35]. It is also a model that was devised by and for healthcare professionals, making it more easily comprehensible and acceptable to the medical field. The UK has adopted legislation that places patients and their decision making needs at the centre of care by making shared decision making the gold standard[36].

Improvement of patient comprehension and informed consent may also be achieved through the use of patient decision aids. Decision aids are clinical tools aimed at complementing the patient-healthcare professional conversation. Their use facilitates understanding of medical conditions, available options, the advantages and disadvantages related to each of them, as well as the scientific uncertainty inherent to some of the information. Specific care is taken to present the information in a way that facilitates its comprehension, even for low-literacy patients[37]. Canadian jurisprudence as yet takes no account of such developments, but in 2007 Washington State adopted "legislation encouraging the use of shared decision making and decision aids to address deficiencies in the informed-consent process[38]." By providing legal protection to healthcare professionals who used a State-approved decision aid with a presumption that informed consent has been obtained, the State has attempted to create legislation based on norms that are shared by all parties.

In the UK, public policies and clinical guidelines go far beyond the legal requirements with respect to informed consent, although their authority is based on the requirements of the law[39]. The National Health Service (NHS) has adopted policies that favour a complete informed consent process and the clinical practice of shared decision making[40]. For example, the NHS is piloting and evaluating interactive web-based decision support tools that patients can access before or after their medical encounter.

35. King and Moulton, supra note 33; Glyn Elwyn et al., « Shared decision making: a model for clinical practice » (2012) 27:10 Journal of General Internal Medicine 1361.
36. Department of Health, Equity and excellence: Liberating the NHS, London, The Stationery Office Limited, 2010.
37. Moulton et al., supra note 33; Dawn Stacey et al., « Decision aids for people facing health treatment or screening decisions » dans Cochrane Database of Systematic Reviews, John Wiley & Sons, Ltd, 2014, online: Cochrane Database of Systematic Reviews <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD001431.pub4/abstract>.
38. Jaime King and Ben Moulton, « Group Health's participation in a shared decision-making demonstration yielded lessons, such as role of culture change » (2013) 32:2 Health Affairs 294, p. 294; State of Washington, An act relating to providing high quality, affordable health care to Washingtonians based on the recommendations of the blue ribbon commission on health care costs and access, Chap 259, 5930SL, May 3rd 2007.
39. M. A. Jones, supra note 20.
40. Glyn Elwyn et al., « Implementing shared decision making in the NHS » (2010) 341 BMJ c5146.

Another possible solution lies in training healthcare professionals to acquire better communication skills. Healthcare professionals need to be better trained to simplify the probabilistic nature of evidence, and acknowledge and discuss scientific uncertainty regarding risks, benefits and alternatives. They also need to learn to solicit patients' questions and opinions, as well as to assess their patients' understanding of medical information[41].

CONCLUSION

Engaging patients in clinical decision-making is more than a trend: it is where our healthcare system is irrevocably going. In order to sustain this movement, legal, medical and patient perspectives on informed consent must be interconnected. The generic consent form for instance, with its static checkbox of criteria to be filled, is of little help to the healthcare professional or the patient. It must evolve to reflect informed consent as a process and a conversation that evolves in a unique manner between a healthcare professional and a patient. Interdisciplinary work is necessary to bring a mutual understanding of what our society expects informed consent to be and achieve innovative and concrete solutions that reflect this shared understanding.

41. Levinson et al., supra note 14; Y. 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.