

Informed consent for clinical treatment

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Although informed consent for clinical treatment has become a vital part of contemporary medical practice, it means different things in different contexts (Figure 1), is variably practised and rarely achieves the theoretical ideal. In this review, we focus on the clinical practice of informed consent. We first describe what we know about informed consent: what it is, where it came from and what purposes it serves. We then describe several limitations that complicate the practice of informed consent. Finally, we make several practical suggestions as to how clinicians might optimally approach the informed consent process.

A summary of the evidence used in this review is available in Box 1.¹ Although we had hoped to identify high-quality studies that would provide a strong quantitative base of evidence for recommendations around informed consent, much of the quantitative literature on this topic is descriptive in nature. Informed consent is primarily a legal and ethical concept; although often informed by data, the standards of scholarship in law and ethics focus on the strength of analytical argument rather than the weight of empirical data. Therefore, we sought to synthesize the available knowledge on this subject, referencing empirical data when possible, summarizing relevant arguments that are particularly prevalent, persuasive or insightful.

What is the purpose of informed consent?

Informed consent has become the primary paradigm for protecting the legal rights of patients and guiding the ethical practice of medicine. It may be used for different purposes in different contexts: legal, ethical or administrative (Figure 1). Although these purposes overlap, they are not identical, thus leading to different standards and criteria for what constitutes “adequate” informed consent.

Legal

Although the concept of consent is rooted in ancient legal and philosophical precepts, the modern legal precedent for “simple” consent was written in 1914, establishing a patient’s “right to deter-

mine what shall be done with his body.”² The further obligation for physicians to disclose details about treatment in a process of informed consent did not emerge until the 1950s,³ when courts first required physicians to disclose information customarily disclosed by experienced clinicians (e.g., the reasonable physician standard). It was not until 1975 that American courts articulated the reasonable person standard, which required that physicians disclose the information that a “reasonable person” would want to know in a similar situation.⁴ Regardless of the standard used, informed consent is further predicated on the patient’s or surrogate’s capacity to make decisions — not only should the decision-maker understand the relevant information, he or she should also be able to appreciate the information’s importance and use it to weigh treatment options in light of their values.⁵

Legally, simple consent protects patients against assault and battery in the form of unwanted medical interventions. The higher standard of informed consent further safeguards patients’ rights to autonomy, self-determination and inviolability. However, the legal standards that apply to obtaining informed consent vary across jurisdictions, and their interpretation continues to evolve. Some jurisdictions use the reasonable person standard, whereas others continue to use the older standard of the reasonable physician. Therefore, it is important for clinicians to determine the precise standard used in their jurisdiction and to adapt their practice accordingly. The Canadian Medical Protective Association provides detailed information on Canadian standards (www.cmpa-acpm.ca). Even

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KEY POINTS

- Informed consent means different things in different contexts, is variably practised and rarely achieves the theoretical ideal.
- Simple consent entails that a patient (or surrogate) with decision-making capacity freely authorizes a treatment plan aimed at a mutually acknowledged treatment goal.
- The authorization is “informed” when the physician discloses and the patient understands the diagnosis, the relevant options for treatment (including no treatment) and any respective risks and benefits.
- The informed consent process should be documented thoroughly, using an electronic medical record, procedure-specific consent forms, patient education materials and other options whenever possible.

when the standard is clear, interpretation is required to apply the standard to a particular case; thus, most litigation regarding informed consent focuses on precisely what information satisfies the applicable standard.⁶ Fortunately, in most cases, legal interpretation is pragmatic; evidence of a good-faith effort to inform is usually found to be adequate.

Ethical

The ethical purpose of informed consent is somewhat more abstract and ideological, seeking to respect patient autonomy by ensuring that treatment is directed toward the ends desired and is chosen by the patient. In this context, informed consent is intended to shift the ethical paradigm for decision-making away from physician-centred models to more patient-centred approaches. The ethics literature regarding informed consent also emphasizes that it is not an event, but a process that precedes the “signing” of the document and continues for as long as the choice remains relevant. Thus, the consent to undergo dialysis or continue with chemotherapy is continually re-evaluated (and may change). The consent form should not be confused with the consent process; the form merely documents that the process has occurred.

Importantly, other parts of the patient record (e.g., clinic and/or operative notes) should corroborate details of the process.

Administrative

For the sake of compliance, the informed consent document serves the administrative purpose of a systems-level check to ensure that a consent process has occurred. Patients simply do not advance to the operating room, for example, without a signed consent form. Unfortunately, pressures for efficient workflow may shift the focus of the informed consent process from robust conversation to the mere requirement of getting a signature.

Although legal and ethical debate persists, most stakeholders in the informed consent process agree on at least four basic elements for discussions of informed consent: the decision-maker (i.e., the patient or a surrogate) should have the capacity to make decisions; the physician should disclose sufficient details for the decision-maker to make an informed choice; the decision-maker should show his or her understanding of the disclosed information; and the decision-maker should freely authorize the treatment plan.

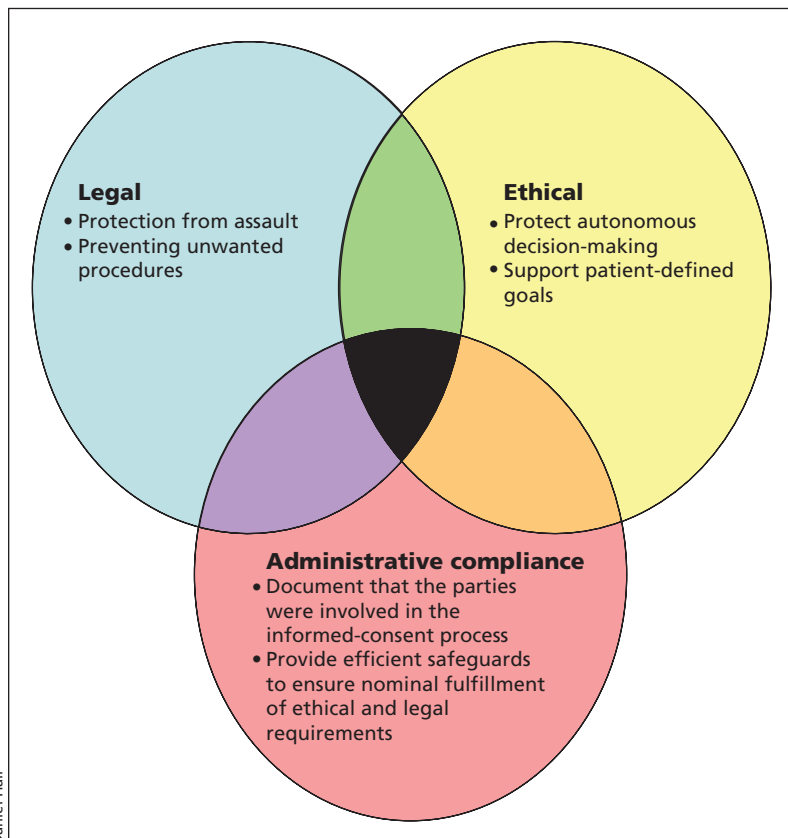
In current clinical practice, these four elements translate into five components that should be included in a discussion seeking to obtain informed consent: the diagnosis, the proposed treatment, the attendant risks and benefits of the treatment, alternative treatments and their risks and benefits, and the risks and benefits of declining treatment.⁷

What factors affect obtaining informed consent?

The practice of informed consent is complicated by several well-documented limitations. These constraints include patient comprehension, patient use of disclosed information, patient autonomy, the demands placed on health care providers and how well physicians meet the minimal standards for disclosure.

Patient comprehension

Data repeatedly show that patients remember little of the information disclosed during the informed consent process^{8–11} and that their level of comprehension is often overestimated.^{12,13} Comprehension is related to factors such as patient age,^{10,14} education,^{9,14,15} intelligence,¹⁰ cognitive function,¹⁰ locus of control¹⁰ and anxiety.⁹ Not surprisingly, the measure also relates to the instrument used to assess comprehension,^{16–18} as well as to the topics covered by the questions asked.^{14,16–18}



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Figure 1: Venn diagram showing the multiple overlapping purposes of informed consent.

Furthermore, patient comprehension and recall deteriorate as time between consent and testing of the patient's understanding increases.^{9,10,16,17}

Patients' use of disclosed information

The theory behind informed consent presumes that patients will use the information disclosed in autonomous and rational ways. Unfortunately, this presumption is not always fulfilled in practice. Although patients are uniformly interested in learning about proposed surgical procedures,^{19–22} the detail desired varies from patient to patient.^{19,21–26} Some patients' preferences for information focus less on decision-making and more on setting realistic expectations for their upcoming surgery.^{27–29} Furthermore, although some patients make decisions in a linear, rational fashion, considering specific risks and benefits, other patients base their decisions on intuition or instinct ("I don't care what you tell me, Doc, the cancer has to come out").^{29–33} Still others may base their decisions on something other than risks and benefits (e.g., the hospital's reputation or patients' subjective assessments of surgeons' commitment to "care" for them).^{34,35}

Even when patients do deliberate over their decisions, the social forces inherent to the health care system can undermine the effectiveness of informed consent. In a qualitative study involving women consenting to gynecological procedures, several patients described feeling compelled to sign the consent form despite their firm preference not to do so.^{36,37} This finding is supported by related survey data showing that 30% of women (220/732) consenting to surgery did not think they had a choice about signing the consent form,³⁸ and that most of the women (88% [642/732]) perceived the form as "just another piece of paper" that satisfied administrative and legal requirements.³⁹

Patient autonomy

Another assumption of informed consent is that patients exercise their autonomy independently. However, qualitative and quantitative data from Canada and the United States suggest that many patients prefer to delegate or defer their decisions to others,^{40,41} or that they prefer to make decisions collaboratively within their support systems.^{42,43} For example, Degner and coauthors found that 57%–59% of patients with cancer from sample populations in Manitoba consistently preferred to delegate all or some of their medical decisions to other people.^{40,41} Furthermore, when patients were asked what was most important about the informed consent process, their responses focused less on decision-making and more on building the trust needed to allow

them to make a "leap of faith" to a surgeon's care.^{34,35} For this reason, critics contend that rather than protecting patients' rights to make decisions as they see fit, informed consent paradoxically mandates that patients make decisions and exercise autonomy in a manner that may be contrary to their preferences and foreign to their experiences.^{29,44}

Demands on providers

A rigorous informed consent process is difficult and takes time from busy clinical schedules. Such time commitments are rarely recognized or rewarded by health care administrators. A recent study measured the time required for providers to obtain informed consent for elective surgery when using an electronic form.⁴⁵ In that study, the mean time taken by the provider was 10.9 minutes, with a large standard deviation (22 min).⁴⁵ Studies involving orthopedic and vascular surgeons showed similar results — the average time needed to obtain consent for orthopedic procedures was 16.1 (range 3–76) minutes;⁴⁶ the average was 12.1 (range 5–20)⁴⁷ minutes for a carotid endarterectomy. These measurements very likely underestimate the true time commitment involved, because they only included the time spent discussing the form. Additional time required for any discussions that the patient may have had with his or her primary care provider before the surgical referral, or with the nurses, midlevel providers or the surgeon in the surgical outpatient area before completing the formal documentation, was not included.

Informed consent also demands maturity and self-awareness on the provider's part to resist the temptation to abandon (or subconsciously

Box 1: Evidence used in this review

This review is based on a broad Medline search for articles pertaining to informed consent in clinical settings, with a focus on surgery. The bibliography was expanded by adding related books and articles developed from reference lists, personal contacts, conference proceedings, and the coauthors' bibliographies. Focused Medline searches regarding specific aspects of informed consent were done as needed to address any gaps in our existing knowledge. The resulting bibliography reflects a bias within the literature toward surgery and other procedural disciplines such as gastroenterology, radiation oncology or interventional radiology. However, the findings in these areas are transferable to other fields of medicine in which physicians must seek their patients' consent for proposed treatment.

The recent systematic review by Schenker and coworkers,¹ in addition to our update of their search, found few "level 1" studies. We noted that much of the literature on the topic of informed consent is descriptive and that there are a wide range of interventions and outcomes tested by the identified randomized comparisons. Our bibliography includes randomized controlled trials, meta-analyses, systematic reviews, qualitative descriptions of patient and physician experience, and observational studies by sociologists and psychologists, in addition to books and articles that examine the law, ethics and policy of informed consent.

subvert) the difficult task of shared decision-making.⁴⁸ For example, a study involving urologists and radiation oncologists showed the unconscious bias of each discipline to its own mode of treatment for a hypothetical case of localized prostate cancer, even though the evidence favoured watchful waiting.⁴⁹ Vigilance is required to manage the subtle ways clinicians favour some treatments over others. However, it is impossible to remove all bias. Physicians must use their clinical experience to make specific recommendations while ensuring that the grounds for these recommendations are as transparent as possible. In the end, shared decision-making ultimately depends on the clinician's ability to discern the degree to which patients can and want to be involved. Although informed consent procedures can assist in this process, they ultimately depend on prudent clinical judgment.

Physicians meeting minimal standards

Research suggests that physicians rarely meet even minimal standards of disclosure for the purposes of obtaining informed consent.⁵⁰⁻⁵⁴ For example, Braddock and colleagues⁵¹ looked at 1057 physician-patient encounters involving 59 primary care physicians and 65 general or orthopedic surgeons. Only 9% of the 2553 clinical decisions made during these encounters met the criteria for completely informed decision-making.

Despite the consensus that informed consent should pervade medical practice, the evidence shows that physicians and patients rarely achieve the theoretical ideal. Indeed, qualitative research suggests that patients and physicians view the consent process primarily as a tool for building trust rather than as a technique for decision-making.^{34,35} However, a discussion with the goal of building trust would not necessarily look the same as a discussion with the goal of decision-making.

How can obtaining informed consent be improved?

The law and ethics of informed consent both reflect and enforce the move from physician-centred to patient-centred decision-making. However, there is increasing recognition that the pendulum may have swung too far, such that some approaches to informed consent go beyond respecting patients' self-determination to mandating that they exercise their autonomy in a very particular way.²⁹

To address this concern, there is a growing focus on a shared process of decision-making — a process that emphasizes the critical importance of patient input while recognizing that it should

be tailored to each patient's ability for and interest in participation, and that the physician's contribution to the decision is important and deserving of its own respect.⁵⁵ To the extent that medical treatment is a partnership between patient and clinician, the moral responsibility for decisions is carried by both partners. Neither partner should dominate the decision, nor should either partner be disenfranchised from their prerogative and privilege to participate as a moral agent in the decision. Support for this paradigm shift was recently articulated by an international consensus panel in the "Salzburg statement on shared decision making" (Appendix 1, available at www.cmaj.ca/lookup/suppl/doi:10.1503/cmaj.112120/-/DC1), which calls on clinicians, patients and policy-makers to change their practices, expectations and laws to more thoroughly share the responsibility for decision-making between clinician and patient.⁵⁶

Another approach argues that informed consent pertains primarily to those decisions that involve choices about the goals of medical treatment. Although this approach has not been tested empirically, Joffe and Truog⁵⁷ suggest that overly rigid interpretations of informed consent confuse and conflate two separate roles of physicians. Joffe and Truog affirm the importance of eliciting patients' values, primarily to allow the physician and patient to reach agreement about the goals of medical care. Having agreed on the goals of care, the physician, as the patient's fiduciary agent, is then free to make decisions about the technical means by which these goals are most effectively achieved.⁵⁷ In our own practice, establishing a clear consensus regarding the intended goals of treatment is certainly one of the most important steps in the informed consent process.

How can informed consent be implemented in practice?

A thorough practice of informed consent is complex, requiring flexibility to address its multiple goals. These goals include the legal goal of protecting patients' rights, the ethical goal of supporting autonomous decision-making, the administrative goal of providing efficient health care and the interpersonal goal of building the trust needed to proceed with therapeutic interventions. The responsibility of clinicians is even greater given the substantial limitations to informed consent. As noted previously, there is little high-quality (i.e., level 1) evidence to guide practice. For this reason, we offer the following comments to support physicians' attempts to meet the ethical and legal ideals of informed

consent. Our suggestions are grounded in the interdisciplinary literature reviewed here, as well as in our own clinical experience practising general surgery and internal medicine.

Involve patients in decision-making

The best way to meet the legal requirements of informed consent is to develop a consistent practice of involving patients in decisions, even if that involvement may occasionally be limited (Box 2).^{1,6,45,58-61} As with any aspect of medical practice, a systematic approach is important. Clinicians can develop a system to ensure that the discussion is not limited to the disclosure of risks, but also includes relevant details about the expected benefits, possible alternatives, and what to anticipate before and after the procedure. Furthermore, clinicians can ensure that the patient or surrogate has the capacity to make decisions, and that the choice is being made voluntarily without undue influence.

Failure to obtain informed consent can lead to legal action. That said, prosecution is rarely successful when there is evidence that the clinician has made a good-faith effort to inform the patient. Furthermore, given that the risk of litigation often depends on patient dissatisfaction due to lack of communication or rapport with the physician,⁶² strong practices for informed consent may actually prevent such suits from being filed. Preliminary evidence suggests that primary care physicians who routinely check their patients' understanding as part of the informed consent process are at reduced risk for law suits.⁶³

Encourage and check patient comprehension

Strategies for improving patients' comprehension of the relevant risks, benefits and alternatives include decision-making worksheets,⁶⁴ standardized and more readable consent forms,^{23,65,66} educational curricula,^{55,67,68} multimedia decision aids,^{69,70} extended discussions⁷¹⁻⁷⁴ and test/feedback techniques.^{45,58,75} Although the Cochrane database identifies more than 200 decision aids and reviews 34 randomized controlled trials designed to improve patient comprehension, the results are mixed.⁵⁹ A recent systematic review¹ identified 44 intervention trials designed to improve patient comprehension during informed consent. Although these interventions generally succeeded in this goal, they focused primarily on procedure-related risks, neglecting relevant alternatives, benefits or general knowledge about the procedure. Only 6 of the 44 trials assessed all four elements of patient comprehension.

Preliminary efforts have been made to incorporate patient-specific risk calculators into

procedure-specific consent forms.^{76,77} It is unclear whether such instruments will change patient decisions or experiences. Although the development of such tools requires a substantial investment of time, often beyond the reach of many physicians, the simple practice of asking patients to repeat what they heard the clinician say can help evaluate a patients' understanding; this practice has improved patient comprehension in several studies.^{45,58,75}

Establish goals of care

It is critically important to establish the goals of care and prioritize them in the context of the patient's other life goals. For common procedures, this may require little clarification, but more explicit discussion will be needed as decisions become more complex. Indeed, effective communication about goals does not necessarily come naturally; some clinicians are better at the informed consent process than others. Whenever

Box 2: Suggestions for optimizing clinical informed consent^{1,6,45,58-61}

- **Develop a practice of involving patients in decisions. This practice should be:**
 - sensitive to patients' preferences for information and their decision-making styles
 - consistently applied to all patients
 - designed to systematically address not only the risks of care, but also the expected benefits, relevant alternatives and what to anticipate before and after the procedure
 - designed to ensure:
 - the decision-making capacity of the patient or surrogate
 - a voluntary choice free of undue influence
 - comprehension (e.g., ask patients to repeat what they heard)
- **Explicitly establish the goals of care, and prioritize them in the context of the patient's other life goals.**
 - Commonly understood goals of care may require little clarification.
 - More explicit discussion will be needed as decisions become more complex.
- **Recognize that the informed consent process serves more than one purpose. Allow the process sufficient flexibility to fulfill its varied purposes:**
 - legal purpose to protect patient rights
 - ethical purpose to support autonomous self-determination and decision-making
 - administrative compliance to promote efficiency in health care
 - interpersonal purpose to build the trust necessary to proceed with therapeutic intervention
- **Document the process thoroughly, using an electronic medical record whenever possible to ensure permanence. This may require more than one approach depending on your local legal, ethical and compliance standards. Techniques may include:**
 - procedure-specific consent forms
 - patient education materials (written and electronic)
 - narrative notes describing the informed consent process and the goals of care
 - decision aids for particularly complex decisions (e.g., treatments for breast cancer)

possible, one should take the opportunity to observe and learn from master clinicians as they engage patients in discussions concerning informed consent.

No treatment is free of risk. Given patients' expectations, it is essential for physicians to emphasize the uncertainty inherent to all medical interventions. Much of the consent process should be directed at establishing reasonable expectations for a treatment's outcome. The language of medicine may impede this goal when terms such as "knee replacement" or "oncological response" seem to promise something more perfect than physicians intend.

Document the process

Clinicians should document the content of these discussions to provide evidence of their good-faith efforts. However, given the diversity of purposes served by the informed consent process, appropriate documentation may require more than one technique. The standardized form best suited for documenting administrative compliance may not be ideally suited for documenting the goals of care or the type of discussion that builds trust. Thus, it may be necessary to use multiple diverse tools to support and document a robust informed consent process.

For particularly complex decisions (e.g., managing breast cancer), Sepucha and colleagues have developed decision aids that seek to define the hierarchy of values each patient considers relevant to a specific decision.^{60,61} Having determined and prioritized those values, the decision aid can assist patients in choosing the therapeutic course (e.g., breast conservation v. prophylactic bilateral mastectomy) that most likely achieves the patient's stated values (e.g., minimally invasive therapy with improved cosmesis v. maximal risk reduction).^{60,61} Similar approaches have been developed for benign prostatic hypertrophy,⁷⁸ and work is in progress to create such tools for joint replacement and heart disease.⁶¹ Although such an approach is not particularly efficient for meeting the legal and bureaucratic imperatives of informed consent, it is one of the best tools for supporting the ethical ideal of informed consent. However, the investment required to develop these tools may not be warranted for less complex decisions such as excising melanoma or repairing inguinal hernias.

One way to clearly document the informed consent discussion is to develop written materials that contain information relevant to the specific procedure. This documentation could take the form of booklets, pamphlets or procedure-specific consent forms, many of which have been developed by individual clinicians, practices and

hospitals. Such resources are perhaps best suited for fulfilling the administrative and legal requirements of informed consent.

There are commercially available products that can support clinicians and patients in the informed consent process. These may provide procedure-specific consent forms and educational materials for patients for medical and surgical specialties, or support their generation locally. Increasingly, Web- or computer-based resources are available, which may be printed or uploaded to an electronic medical record.

Two recent studies have shown that a computer-based consent tool improved patients' comprehension of procedure-specific risks, benefits and alternatives from 50% to 60%,⁷² with a dose-response suggesting that comprehension improves as more time (up to 15 min) is spent with the resource.⁵⁸ Another tool, which is accessed online, improved patient satisfaction and self-rated comprehension for gastric bypass, total knee arthroscopy and colonoscopy.⁷⁶ When compared with written consent forms, the online tool objectively improved patient comprehension of procedure-specific risk, benefits and alternatives for diagnostic esophagogastros-copy.⁷⁷ However, as with other enhancements, only 33% of participants using this tool achieved "adequate" informed consent as defined by researchers, reinforcing ongoing uncertainty about the criteria available for assessing the adequacy of informed consent.

Audiovisual and multimedia resources that teach patients about specific procedures or decisions offer another approach for enhancing informed consent. Although such tools can provide substantive evidence of the effort to inform patients, their focus is often less on documentation than on patient education. A review by Schenker and coworkers describes 15 audiovisual tools, of which 11 improved patient comprehension.¹ Unfortunately, substantial investments of time and money were required to develop these tools.

Conclusion

Having emerged from multiple disciplines, research concerning informed consent does not afford sufficient clarity or consensus regarding the purposes this process serves or the standards by which it should be judged. Our pragmatic suggestions aim to facilitate — and document — a good-faith effort to involve patients in medical decisions to whatever degree they are interested and able. Such practice complies with the ethical spirit of informed consent and should minimize legal conflict by fostering a deep and nuanced respect for patients.

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