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A Typology of Shared Decision Making, Informed Consent, and Simple Consent

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Enhancing patient choice is a central theme of medical ethics and law. Informed consent is the legal process used to promote patient autonomy; shared decision making is a widely promoted ethical approach. These processes may most usefully be seen as distinct in clinically and ethically important respects. The approach outlined in this article uses a model that arrays all medical decisions along 2 axes: risk and certainty. At the extremes of these continua, 4 decision types are produced, each of which constrains the principal actors in predictable ways. Shared decision making is most appropriate in situations of uncertainty, in which 2 or more clinically reasonable alternatives exist. When there is only 1 realistic choice, patient and physician may gather and exchange information; however, the patient cannot be empowered to make choices that do not exist. In contrast, informed consent does not require the presence of clinical choice; it is appropriate for all decisions of significant risk, even if there is only one option. When a clinical decision contains both risk and uncertainty, shared decision making and informed consent are both appropriate. For decisions of lower risk, consent should still be present, but it can be simple rather than informed. Clinicians may use this analysis as a guide to their own interactions with patients. In the continuing effort to provide patients with appropriate decisional authority over their own medical choices, shared decision making, informed consent, and simple consent each has a distinct role to play.

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The patient and the physician play distinct roles in medical decision making. The physician is usually the first to recommend a particular course of action and thus is in a position that we call *decisional priority,* a phrase that is meant to imply antecedence but not superiority. The competent adult patient, who reaps the rewards or suffers the consequences of any intervention, retains final decisional authority, an authority that is delegated to family or surrogate when the patient cannot make decisions.

The patient's participation in clinical decisions is fostered by the legal doctrines of consent and informed consent and by the ethical process of shared decision making. Shared decision making, which is closely related to such concepts as patient-centered care, patient empowerment, and evidence-based patient choice, is a collaborative endeavor in which patient and physician share not only information and intuitions but the making of decisions (1–4). Although informed consent and the sharing of decisions with patients are widely acknowledged as essential components of good care, there is no agreement on how these concepts are related, and their potential for improving the interaction between patient and physician or other health care provider has been only imperfectly realized. Many perceive the patient–physician interaction as stubbornly limited, with the physician often providing scanty information and offering minimal decisional authority to patients (5–7).

We explore these issues, with an emphasis on an easily overlooked element: the actual decision at hand, which can vary widely. Medical interventions are of many types, including lifestyle, diagnostic, pharmacologic, radiotherapeutic, and surgical, but our emphasis is not on these apparent differences. We look instead at the underlying characteristics of decisions, which create commonalities and distinctions that bear directly on the interaction between patient and physician. We used these characteristics to build a model of medical decision making, which we then used to analyze the difference between informed consent and shared decision making. We hope that this analysis will provide clinicians with helpful insights. Physicians who understand these complex dynamics will be better able to navigate these deceptively complex processes and thereby promote better patient satisfaction, compliance, and treatment outcomes.

Two Processes, One Goal?

Because informed consent and shared decision making can serve the same purpose—to enhance the patient's control over his or her medical care—it is natural to ask whether they are, or should be, the same process, as some commentators have asserted (1, 8). Two means, one developed for the most part in ethics (shared decision making) and the other developed primarily in law (informed consent), could both operate to create the same collaborative environment and serve the same goal.

This possibility is strengthened by our evolving understanding of informed consent. Ethically, informed consent is an individual's autonomous authorization of a medical intervention, but it is also a formal process that institutions require before permitting procedures (9, 10) and a legal undertaking aimed at reducing physicians' liability. The heart of informed consent, however, is a conversation between physician and patient about a proposed treatment, alternative treatments, nontreatment, and the risks and benefits of each of these options (1, 8, 11). Informed consent does not happen when a form is signed; it occurs when patient and physician discuss a problem and choose an intervention together, a process that may take place in 1 sitting or over the course of several encounters (12–14).

Table 1. **Simple Consent versus Informed Consent**

Characteristic	Simple Consent	Informed Consent
Type of decision	Low risk	High risk
Elements	Explanation of intervention, followed by patient agreement or refusal (expressed or implied); other elements, such as discussion of risks, benefits, and alternatives are present when appropriate	Discussion of nature, purpose, risks and benefits of proposed intervention, any alternatives, and no treatment, followed by explicit patient agreement or refusal

The minimal result of informed consent is the patient's decision to accept or refuse a proposed intervention. Fuller engagement of the patient, however, holds promise for a more satisfying choice and perhaps better outcomes. When this view is taken, informed consent, like shared decision making, is a framework in which physicians should think about and relate to their patients in every clinical encounter. The legal rules recede, and the spirit of those rules, one of profound respect for the right of every patient to chart his or her own course, emerges. Informed consent is no longer tied to the narrow confines of consent as permission to perform a procedure; it becomes an automatic, unconscious part of the entire enterprise of medical care. Informed consent becomes shared decision making.

This argument is alluring but does not survive close analysis, because there are ethically and clinically important distinctions between shared decision making and informed consent. The concept of simple consent plays an important role in this broader understanding of how patients and physicians share information and authority. We begin with a close analysis of the scope of each of these decision processes.

The Scope of Informed Consent and Simple Consent

The legal scope of informed consent hinges on risk. In the United States, except when a state statute specifies otherwise, the general legal rule is that informed consent is required only when an intervention, or a failure to intervene, poses a significant risk for harm. As a corollary to this rule, if informed consent involves making medical decisions on the basis of considerations of risk versus benefit, then when little or no risk exists, the decision-making process that ensues is something other than informed consent. Risk is a continuous phenomenon: The risk of any particular intervention reflects the probability and severity of the possible adverse events. Our analysis focuses on the high and low end points of the risk spectrum. "High risk" means that the probability of serious or irreversible adverse events from either intervention or nonintervention is significant. Functionally, we define an intervention as being high risk if the physician requests the patient's permission through the informed consent process before proceeding.

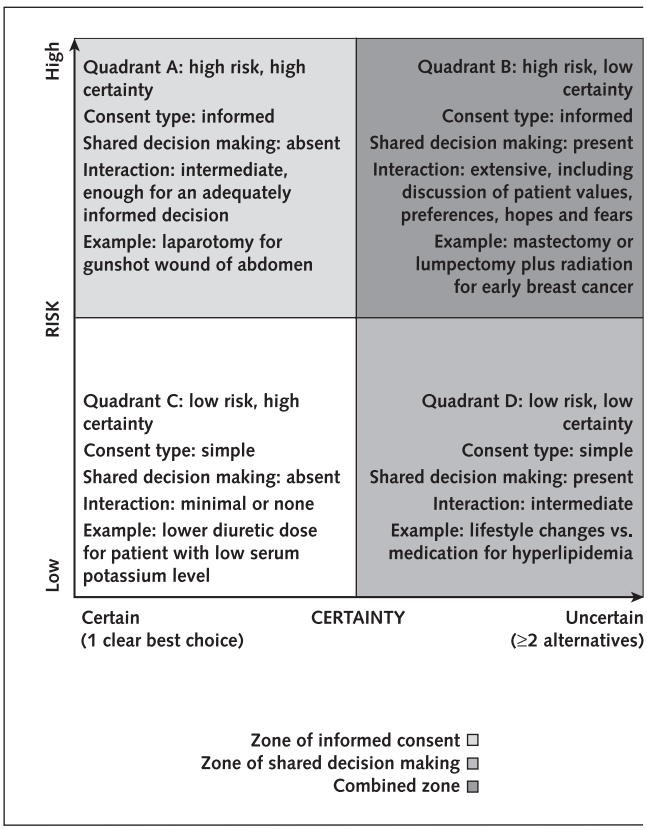
Many medical choices are low risk: They entail predictable adverse events that are of low incidence and are readily clinically manageable. Consider, for example, a patient with contact dermatitis due to a ring that contains nickel. Informed consent, including a discussion of how a topical corticosteroid will help and the risks and benefits of using this medication on a finger, would be a waste of time. The physician should simply explain what is wrong, how to use the medication, what to do about the ring, and ask the patient whether he or she has questions. This process is not informed consent, because there is no discussion of risk or alternative treatments and the patient's agreement is assumed.

One could argue that this discussion is still a kind of informed consent, but that begs the question of whether it is useful to view it that way. It is more appropriate to view this discussion about the topical corticosteroid, followed by the patient's decision to fill the prescription and administer the medication, as constituting simple consent: agreeing or not agreeing to a proposed plan of care (**Table 1**). Some type of consent is required for every medical intervention. In informed consent, the consent is always expressed, meaning that the patient explicitly authorizes the intervention, but simple consent may be indicated implicitly, for example, by accepting and filling a prescription (15) or by choosing fish instead of steak when advised to eat a more heart-healthy diet. Simple consent is ethically adequate for low-risk decisions, whereas informed consent is required for high-risk decisions. For high-risk decisions, patient and physician should engage in the full informed consent process, which is a balanced and individualized consideration of the risks and benefits of each available alternative.

The Scope of Shared Decision Making

Shared decision making involves an exchange of ideas between patient and physician and collaboration in the decision itself (1–3). Shared decision making in its fullest sense occurs only when real choice exists and the physician involves the patient in the decision. A physician may sometimes make a decision unilaterally, obtaining the patient's consent without offering the patient a choice in the matter; this is not a shared decision. It is common for physicians to share information but not decisional authority in this way (5–7). Often, it would be better for the physician to include the patient in the decision making, and when the choice hinges on personal values (such as the patient's moral and religious beliefs) or personal preferences (such as the patient's desire to remain mentally alert even if it

Figure. **Decision plane showing the distribution of simple consent, informed consent, and shared decision making within 4 types of medical decisions.**



means enduring more pain), the patient should be offered unfettered decisional authority. Although patients have broad rights to make their own decisions, we make no claim that they have a general duty to do so; many patients, for a variety of reasons, choose to delegate decisional authority to their physicians (16).

When a patient makes an independent choice, the decision making is unilateral and not shared, but because the same ethical arguments that favor sharing of decisional power encourage the patient to accept full responsibility when appropriate, we will incorporate these patient-dominated choices under the favorable canopy of shared decisions. Physicians should extend an invitation to participate in medical decisions to all patients who confront substantial competing treatment choices. Physicians should empower patients, not disempower them.

However, some patients are disempowered by their illness. A patient with a gunshot wound to the abdomen and unstable vital signs must undergo surgery promptly. Granted, he could choose no treatment and would probably die, but most physicians see no choice in this circumstance and most patients agree. Because there is only one medically reasonable alternative in this situation, the concept of shared decision making does not apply here. This assertion is concordant with some accounts of shared decision making that are explicitly limited to situations in which more than one choice exists (2, 4, 17), and with research suggesting that physicians believe that shared decision making is particularly appropriate in situations for which there is no professional consensus on the best treatment (18).

Mapping Consent and Shared Decision Making

Because of these differences in scope and content, informed consent and shared decision making may most usefully be seen as normatively distinct, each with a characteristic place in the medical encounter. We use a standardized model to demonstrate how each of these processes applies to a different set of medical decisions with distinct allocations of decisional responsibility between patient and physician.

We first array all medical decisions on a surface whose axes are risk and certainty, which are continuous phenomena. This produces a geometrically structured typology that is based on the underlying characteristics of each choice, regardless of the superficial differences among decisions. We call this two-dimensional surface a *decision plane* (19) (**Figure**). In addition to the variation among decisions, different patients and physicians will have different opinions on whether a particular intervention is high or low risk, or whether a particular decision presents more than 1 acceptable treatment alternative. We therefore focus our analysis on the limits at the ends of these continua, which combine to form 4 quadrants.

We use this model to examine how simple consent, informed consent, and shared decision making map onto this decision plane. The examples presented below are taken from the **Figure**.

Informed Consent

Informed consent is needed in decisions involving high risk; it applies equally to situations in which only 1 appropriate choice exists and those in which 2 or more choices exist (**Figure**, *quadrants A* and *B*). The competent adult patient with a gunshot wound to the abdomen needs surgery; he has no real choice. He should nonetheless be informed about the benefits and risks of the surgery, and he is free to refuse it. Because only 1 choice exists, informed consent in this situation is primarily an educational process, not an aid in making the decision. If time allows, the patient should be told about the possibility of bleeding, infection, injury to organs, and the potential need for a colostomy or splenectomy. If his condition is unstable, this discussion should be abbreviated or omitted, because consent is legally presumed in an emergency and informed consent should not interfere with the provision of prompt, effective care.

The patient with a small, localized breast cancer may also accept or reject a mastectomy through the process of informed consent, but her situation differs in 2 important

respects. Because lumpectomy with radiation would be an appropriate alternative treatment, this patient has genuine freedom of choice, and there is ample time to fully inform her of the advantages and disadvantages of each alternative.

Simple Consent

Simple consent applies in decisions of low risk, including cases in which there is 1 clear best choice and those in which medically reasonable alternatives exist (**Figure**, *quadrants C* and *D*). As an example, a patient with an elevated cholesterol level might choose lifestyle changes alone or lifestyle changes and medication. If the patient does not have a strong preference for one choice, the physician's task is to provide information, elicit the patient's beliefs and preferences, and answer his or her questions so that an adequately informed decision may be made. This is a simple consent process that may expand to look very much like informed consent if the patient is uncertain and inquisitive. In contrast, a patient receiving diuretic therapy who develops a low serum potassium level may simply be told, "Your blood pressure is fine, but your potassium is too low, so I'm going to reduce your medication dose." In either case, the education provided should fit the circumstances and the patient's level of interest.

Shared Decision Making

Shared decision making is appropriate for situations in which 2 or more medically reasonable choices exist, regardless of whether the degree of risk is high or low (**Figure**, quadrants B and D). Because mastectomy and lumpectomy with radiation produce indistinguishable cure rates for early breast cancer, the choice between these techniques should be value based. Some women want the breast removed to eliminate their worries about recurrence, whereas others are more concerned about the effect on their sexuality and body image. Cost, convenience, time off work, and the need for travel are also relevant for many women. In this situation of curative equivalence, each woman should make the decision that best meets her emotional and situational needs. To help her do so in a thoughtful way, her physician should provide her with information and advice, elicit her values, and work with her as she makes her decision. Although the patient with a moderately elevated cholesterol level who must choose between lifestyle changes and medication faces a less momentous decision, it is equally his to make.

These considerations determine the decision set to which each process is relevant. For decisions that are high risk and have more than one choice (**Figure**, *quadrant B*), informed consent and shared decision making are both applicable. These important decisions demand much from the physician, who should take time to explore the patient's values, concerns, and emotional and social needs; educate the patient and the family about the problem; and outline the available choices. The goal is to reach a choice that feels right to the patient. Although the physician should not shrink from offering guidance, these decisions should ultimately come from the patient, who will live with the consequences of her choice.

In contrast, for decisions that are high risk and have only 1 choice (**Figure**, *quadrant A*), shared decision making is inapposite, because rational patients will ordinarily choose the medically appropriate intervention. If time allows, the patient with a gunshot wound to the abdomen should be educated about his condition and the proposed surgery, but the discussion of the alternative treatment, expectant management, will be framed in such a way as to make it clear that this approach is known to increase morbidity and mortality. The patient will still make the final decision for or against surgery, but his hand is forced, not by his physician's coercion but by the exigencies of his condition.

For all low-risk decisions, simple consent, adapted to the situation, is sufficient. In obtaining simple consent, physicians may include some elements of the informed consent process, such as discussion of alternatives or a probe to assess the patient's understanding. Such conversations do not constitute impaired informed consent; rather, the physician tailors the conversation to the needs of a particular patient making a particular decision. Of note, consent appears in all 4 cells of the figure. Nowhere do we advocate paternalism, only for a distinction between simple and informed consent.

Low-risk decisions that involve more than 1 treatment option are to be managed with shared decision making, but not the more demanding process of informed consent (**Figure**, *quadrant D*). Patients with low-risk problems for which a single suitable treatment exists may be engaged by a simple consent process alone, without the assistance of shared decision making or informed consent (**Figure**, *quadrant C*). All that is required is that the physician inform the patient of his or her recommendation; the patient may consent, ask for more information, or decline. In the case of a patient taking diuretics who is found to have a low potassium level, it is ethically appropriate for a member of the physician's staff to notify the patient that his potassium level is too low and that the dose of diuretic is therefore being reduced. Certainly, some patients will wish to discuss the situation with their physician in person, but in the absence of indications that the low potassium level indicates another problem, we believe that most patients will gladly forgo the time and expense of an office visit to learn more about such an unimportant decision over which they have so little influence. This belief is consistent with Schneider's observation that most patients believe that much of medical decision making should be left to physicians (16). In contrast, some choices should not be left to physicians; enhanced patient participation is particularly appropriate for the types of decisions shown in **Table 2**.

Although this formulation may be novel, physicians have long recognized the role of uncertainty in medical practice (20–22). Investigators continue to recognize that the extent of patient involvement in decisions should log-

Table 2. **Decision Types for Which Augmented Patient Involvement Is Particularly Important**

Type of Decision	Characteristic	Appropriate Interaction	Example
High risk	Significant chance of adverse effects	Obtain informed consent	Isotretinoin to treat severe acne in a fertile woman
Medically uncertain	The physician is uncertain of the right course of action, or other clinicians might have different recommendations	(See subtypes below)	
Medically uncertain and preference sensitive	Choice involves trade-off between length and quality of life, or such competing considerations as preservation of bodily integrity, prevention of future problems, cost, and convenience	Encourage the patient to participate in the decision after discussing the choices	Mastectomy versus lumpectomy plus radiation to treat small, localized breast cancer
Medically uncertain and value sensitive	Choice is likely to vary with religious, moral, and philosophical beliefs of patient	Encourage the patient to make the decision after discussing the choices	Amniocentesis to screen for prenatal genetic defects

ically vary, with major decisions meriting a fuller patient education and involvement process than do minor decisions (6, 7).

The confusion between informed consent and shared decision making and the expansion of informed consent and shared decision making to govern all medical decisions are largely due to early preoccupation in medical ethics with dramatic cases. Typically, cases were of major importance and high uncertainty in which patients' values, and hence shared decision making, were highly relevant (for example, continuing life support for patients in a persistent vegetative state, surgery for localized breast cancer, or care or termination of care for severely burned persons). This literature neglected a second class of major decisions, those for which patient preferences are irrelevant because 1 optimal treatment path exists. In this type of decision, informed consent is important but shared decision making is irrelevant. Similarly, the ethics literature has paid scant attention to minor decisions that do not require informed consent but should involve shared decision making.

Our model of decision making predicts that patients and physicians will intuitively act in different ways as the decision characteristics change. This prediction is open to modification or rebuttal. Our group is interviewing physicians to learn how they structure decision making with patients. In a study relevant to decisions of high risk and high certainty (**Figure**, *quadrant A*), Jacoby and colleagues (23) studied the informed consent process for patients with cancer who were considering bone marrow transplantation, the only treatment option that provided the possibility of cure. They found informed consent to meet patients' "emotional rather than cognitive needs."

Our model also suggests a new way to view informed consent in medical research. The patient who is considering participating in research still confronts a choice involving certainty and risk, but the nature of the research intervention adds a minimum of 1 additional axis, such as the extent to which the experimental therapy is superior to any available intervention. Here, the result is a decision cube (or hypercube) that may fruitfully be examined for the unique circumstances inherent in different research scenarios. We suggest that the research consent process might need to be prepared and administered differently as these circumstances change.

We believe that physicians will share our view of informed consent and shared decision making as mapping onto 2 overlapping but conceptually distinct realms. This approach also suggests 1 answer to the puzzle of why physicians appear reluctant to share decisional authority with patients: Sometimes sharing decisional authority is imperative, but sometimes it simply does not make sense. Although we argue that the allocation of decisional responsibility should vary among different decision types, we make no claim that physicians consistently manage the decision process appropriately. Clearly, there are times when physicians offer too little decisional authority to their patients, just as at times they offer too little support. Our hope is that this description will help physicians understand how decisional priority and authority should vary over decisions.

It is tempting to merge the legal power of informed consent with the moral authority of shared decision making. Recognizing these processes as distinct allows us to correct some misperceptions about the relationship among the patient, the physician, and the decision. Decisions for which a single correct clinical response exist call for patient education and, if the intervention is major, for informed consent, but there is little room for shared decision making. This is one explanation for the reluctance of physicians to share decisional priority with patients: For some deci-

sions, the patient retains decisional authority but will ordinarily make the choice suggested by the physician. This yielding of decisional priority reflects the constraints imposed on the patient by his or her disease rather than paternalism on the part of the physician. Conversely, the physician may encourage the patient to make a choice when there are 2 or more valid treatment options, each of low risk, without needing to invoke the concept of informed consent. Patient and physician thus play very different roles for different decision types. This variation is neither good nor bad; it is a natural and inevitable result of the changing situation of patient and physician as they confront decisions of different kinds.

This normative account accommodates physicians' values while recognizing the continued central importance of patients' rights and responsibilities to make their own choices. Informed consent enhances patient control in situations of significant risk, and shared decision making applies when there are two or more reasonable medical options. We thus modify the current account of informed consent in the following way: Consent is always required, but informed consent is not.

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