While the patient's right to give informed consent to medical treatment is now well-established both in U.S. law and in biomedical ethics, evidence continues to suggest that the concept has been poorly integrated into American medical practice, and that in many instances the needs and desires of patients are not being well met by current policies. It appears that the theory and the practice of informed consent are out of joint in some crucial ways. This is particularly true for primary care settings, a context typically ignored by medical ethics literature, but where the majority of doctor-patient encounters occur. Indeed, some have suggested that the concept of informed consent is virtually foreign to primary care medicine where benign paternalism appropriately reigns and where respect for patient autonomy is almost completely absent.

It is worth asking whether current legal standards for informed consent tend to resolve the problem or to exacerbate it. I will maintain that accepted legal standards, at least in the form commonly employed by courts, send physicians the wrong message about what is expected of them. An alternative standard that would send physicians the correct message, a conversation standard, is probably unworkable legally. As an alternative, I will propose a transparency standard as a compromise that gives physicians a doable task and allows courts to review appropriately. I must begin, however, by briefly identifying some assumptions crucial to the development of this position even though space precludes complete argumentation and documentation.

**Crucial Assumptions**

Informed consent is a meaningful ethical concept only to the extent that it can be realized and promoted within the ongoing practice of good medicine. This need not imply diminished respect for patient autonomy, for there are excellent reasons to regard respect for patient autonomy as a central feature of good medical care. Informed consent, properly understood, must be considered an essential ingredient of good patient care, and a physician who lacks the skills to inform patients appropriately and obtain proper consent should be viewed as lacking essential medical skills necessary for practice. It is not enough to see informed consent as a nonmedical, legalistic exercise designed to promote patient autonomy, one that interrupts the process of medical care.

However, available empirical evidence strongly suggests that this is precisely how physicians currently view informed consent practices. Informed consent is still seen as bureaucratic legalism rather than as part of patient care. Physicians often deny the existence of realistic treatment alternatives, thereby attenuating the perceived need to inform the patient of meaningful options. While patients may be informed, efforts are seldom made to assess accurately the patient's actual need or desire for information, or what the patient then proceeds to do with the information provided. Physicians typically underestimate patients' desire to be informed and overestimate their desire to be involved in decisionmaking. Physicians may also view informed consent as an empty charade, since they are confident in their abilities to manipulate consent by how they discuss or divulge information.

A third assumption is that there are important differences between the practice of primary care medicine and the tertiary care settings that have been most frequently discussed in the literature on informed consent. The models of informed consent discussed below typically take as the paradigm case something like surgery for breast cancer or the performance of an invasive and risky radiologic procedure. It is assumed that the risks to the patient are significant, and the values placed on alternative forms of treatment are quite weighty. Moreover, it is assumed that the specialist physician performing the procedure probably does a fairly limited number of procedures and thus could be expected to know exhaustively the precise risks, benefits, and alternatives for each.

Primary care medicine, however, fails to fit this model. The primary care physician, instead of performing five or six complicated and risky procedures frequently, may engage in several hundred treatment modalities during an average week of practice. In many cases, risks to the patient are negligible and conflicts over patient values and the goals of treatment or nontreatment are of little consequence. Moreover, in contrast to the tertiary care patient, the typical ambulatory patient is much better able to exercise freedom of choice and somewhat less likely to be
intimidated by either the severity of the disease or the expertise of the physician; the opportunities for changing one's mind once treatment has begun are also much greater. 

Indeed, in primary care, it is much more likely for the full process of informed consent to treatment (such as the beginning and the dose adjustment of an anti-hypertensive medication) to occur over several office visits rather than at one single point in time.

It might be argued that for all these reasons, the stakes are so low in primary care that it is fully appropriate for informed consent to be interpreted only with regard to the specialized or tertiary care setting. I believe that this is quite incorrect for three reasons. First, good primary care medicine ought to embrace respect for patient autonomy, and if patient autonomy is operationalized in informed consent, properly understood, then it ought to be part and parcel of good primary care. Second, the claim that the primary care physician cannot be expected to obtain the patient's informed consent seems to undermine the idea that informed consent could or ought to be part of the daily practice of medicine. Third, primary care encounters are statistically more common than the highly specialized encounters previously used as models for the concept of informed consent.4

**Accepted Legal Standards**

Most of the literature on legal approaches to informed consent addresses the tension between the community practice standard and the reasonable patient standard, with the latter seen as the more satisfactory, emerging legal standard.5 However, neither standard sends the proper message to the physician about what is expected of her to promote patient autonomy effectively and to serve the informational needs of patients in daily practice.

The community practice standard sends the wrong message because it leaves the door open too wide for physician paternalism. The physician is instructed to behave as other physicians in that specialty behave, regardless of how well or how poorly that behavior serves patients' needs. Certainly, behaving the way other physicians behave is a task we might expect physicians to readily accomplish; unfortunately, the standard fails to inform them of the end toward which the task is aimed.

The reasonable patient standard does a much better job of indicating the centrality of respect for patient autonomy and the desired outcome of the informed consent process, which is revealing the information that a reasonable person would need to make an informed and rational decision. This standard is particularly valuable when modified to include the specific informational and decisional needs of a particular patient.

If certain things were true about the relationship between medicine and law in today's society, the reasonable patient standard would provide acceptable guidance to physicians. One feature would be that physicians esteem the law as a positive force in guiding their practice, rather than as a threat to their well-being that must be handled defensively. Another element would be a prospective consideration by the law of what the physician could reasonably have been expected to do in practice, rather than a retrospective review armed with the foreknowledge that some significant patient harm has already occurred.

Unfortunately, given the present legal climate, the physician is much more likely to get a mixed or an undesirable message from the reasonable patient standard. The message the physician hears from the reasonable patient standard is that one must exhaustively lay out all possible risks as well as benefits and alternatives of the proposed procedure. If one remembers to discuss fifty possible risks, and the patient in a particular case suffers the fifty-first, the physician might subsequently be found liable for incomplete disclosure. Since lawsuits are triggered when patients suffer harm, disclosure of risk becomes comparatively more important than disclosure of benefits. Moreover, disclosure of information becomes much more critical than effective patient participation in decisionmaking. Physicians consider it more important to document what they said to the patient than to document how the patient used or thought about that information subsequently.

In specialty practice, many of these concerns can be nicely met by detailed written or videotaped consent documents, which can provide the depth of information required while still putting the benefits and alternatives in proper context. This is workable when one engages in a limited number of procedures and can have a complete document or videotape for each.6 However, this approach is not feasible for primary care, when the number of procedures may be much more numerous and the time available with each patient may be considerably less. Moreover, it is simply not realistic to expect even the best educated of primary care physicians to rattle off at a moment's notice a detailed list of significant risks attached to any of the many drugs and therapeutic modalities they recommend.

This sets informed consent apart from all other aspects of medical practice in a way that I believe is widely perceived by nonpaternalistic primary care physicians, but which is almost never commented upon in the medical ethics literature. To the physician obtaining informed consent, you never know when you are finished. When a primary care physician is told to treat a patient for strep throat or to counsel a person suffering a normal grief reaction from the recent death of a relative, the physician has a good sense of what it means to complete the task at hand. When a physician is told to obtain the patient's informed consent for a medical intervention, the impression is quite different. A list of all the possible risks as can be thought of may still omit some significant ones. A list of all the risks that actually have occurred may still not have dealt with the patient's need to know risks in relation to benefits and alternatives. A description of all benefits, risks, and alternatives may not establish whether the patient has understood the information. If the patient says he understands, the physician has to wonder whether he really understands or whether he is simply saying this to be accommodating. As the law
According to the transparency model, the key to reasonable disclosure is not adherence to existing standards of other practitioners, nor ... to a list of risks that a hypothetical reasonable patient would want to know. Instead, disclosure is adequate when the physician's basic thinking has been rendered transparent to the patient.

The Conversation Model

A metaphor employed by Jay Katz, informed consent as conversation, provides an approach to respect for patient autonomy that can be readily integrated within primary care practice. Just as the specific needs of an individual patient for information, or the meaning that patient will attach to the information as it is presented, cannot be known in advance, one cannot always tell in advance how a conversation is going to turn out. One must follow the process along and take one's cues from the unfolding conversation itself. Despite the absence of any formal rules for carrying out or completing a conversation on a specific subject, most people have a good intuitive grasp of what it means for a conversation to be finished, what it means to change the subject in the middle of a conversation, and what it means to later reopen a conversation one had thought was completed when something new has just arisen. Thus, the metaphor suggests that informed consent consists not in a formal process carried out strictly by protocol but in a conversation designed to encourage patient participation in all medical decisions to the extent that the patient wishes to be included. The idea of informed consent as physician-patient conversation could, when properly developed, be a useful analytic tool for ethical issues in informed consent, and could also be a powerful educational tool for highlighting the skills and attitudes that a physician needs to successfully integrate this process within patient care.

If primary care physicians understand informed consent as this sort of conversation process, the idea that exact rules cannot be given for its successful management could cease to be a mystery. Physicians would instead be guided to rely on their own intuitions and communication skills, with careful attention to information received from the patient, to determine when an adequate job had been done in the informed consent process. Moreover, physicians would be encouraged to see informed consent as a genuinely mutual and participatory process, instead of being reduced to the one-way disclosure of information. In effect, informed consent could be demystified, and located within the context of the everyday relationships between physician and patient, albeit with a renewed emphasis on patient participation.

Unfortunately, the conversation metaphor does not lend itself to ready translation into a legal standard for determining whether or not the physician has satisfied her basic responsibilities to the patient. There seems to be an inherently subjective element to conversation that makes it ill-suited as a legal standard for review of controversial cases. A conversation in which one participates is by its nature a very different thing from the same conversation described to an outsider. It is hard to imagine how a jury could be instructed to determine in retrospect whether or not a particular conversation was adequate for its purposes. However, without the possibility for legal review, the message that patient autonomy is an important value and that patients have important rights within primary care would seem to be severely undermined. The question then is whether some of the important strengths of the conversation model can be retained in another model that does allow better guidance.

The Transparency Standard

I propose the transparency standard as a means to operationalize the best features of the conversation model in medical practice. According to this standard, adequate informed consent is obtained when a reasonably informed patient is allowed to participate in the medical decision to the extent that patient wishes. In turn, "reasonably informed" consists of two features: (1) the physician discloses the basis on which the proposed treatment, or alternative possible treatments, have been chosen; and (2) the patient is allowed to ask questions suggested by the disclosure of the physician's reasoning, and those questions are answered to the patient's satisfaction.

According to the transparency model, the key to reasonable disclosure is not adherence to existing standards of other practitioners, nor is it adherence to a list of risks that a hypothetical reasonable patient would want to know. Instead, disclosure is adequate when the physician's basic thinking has been rendered transparent to the patient. If the physician arrives at a recommended therapeutic or diagnostic intervention only after carefully examining a list of risks and benefits, then rendering the physician's thinking transparent...
requires that those risks and benefits be detailed for the patient. If the physician's thinking has not followed that route but has reached its conclusion by other considerations, then what needs to be disclosed to the patient is accordingly different. Essentially, the transparency standard requires the physician to engage in the typical patient-management thought process, only to do it out loud in language understandable to the patient.\(^8\)

To see how this might work in practice, consider the following as possible general decision-making strategies that might be used by a primary physician:

1. The intervention, in addition to being presumably low-risk, is also routine and automatic. The physician, faced with a case like that presented by the patient, almost always chooses this treatment.

2. The decision is not routine but seems to offer clear benefit with minimal risk.

3. The proposed procedure offers substantial chances for benefit, but also very substantial risks.

4. The proposed intervention offers substantial risks and extremely questionable benefits. Unfortunately, possible alternative courses of action also have high risk and uncertain benefit.

The exact risks entailed by treatment loom much larger in the physician's own thinking in cases 3 and 4 than in cases 1 and 2. The transparency standard would require that physicians at least mention the various risks to patients in scenarios 3 and 4, but would not necessarily require physicians exhaustively to describe risks, unless the patient asked, in scenarios 1 and 2.

The transparency standard seems to offer some considerable advantages for informing physicians what can legitimately be expected of them in the promotion of patient autonomy while carrying out the activities of primary care medicine. We would hope that the well-trained primary care physician generally thinks before acting. On that assumption, the physician can be told exactly when she is finished obtaining informed consent—first, she has to share her thinking with the patient; secondly, she has to encourage and answer questions; and third, she has to discover how participatory he wishes to be and facilitate that level of participation. This seems a much more reasonable task within primary care than an exhaustive listing of often irrelevant risk factors.

There are also considerable advantages for the patient in this approach. The patient retains the right to ask for an exhaustive recital of risks and alternatives. However, the vast majority of patients, in a primary care setting particularly, would wish to supplement a standardized recital of risks and benefits of treatment with some questions like, "Yes, doctor, but what does this really mean for me? What meaning am I supposed to attach to the information that you've just given?" For example, in scenarios 1 and 2, the precise and specific risk probabilities and possibilities are very small considerations in the thinking of the physician, and reciting an exhaustive list of risks would seriously misstate just what the physician was thinking. If the physician did detail a laundry list of risk factors, the patient might very well ask, "Well, doctor, just what should I think about what you have just told me?" and the thoughtful and concerned physician might well reply, "There's certainly a small possibility that one of these bad things will happen to you; but I think the chance is extremely remote and in my own practice I have never seen anything like that occur." The patient is very likely to give much more weight to that statement, putting the risks in perspective, than he is to the listing of risks. And that emphasis corresponds with an understanding of how the physician herself has reached the decision.

The transparency standard should further facilitate and encourage useful questions from patients. If a patient is given a routine list of risks and benefits and then is asked "Do you have any questions?" the response may well be perfunctory and automatic. If the patient is told precisely the grounds on which the physician has made her recommendation, and then asked the same question, the response is much more likely to be individualized and meaningful.

There certainly would be problems in applying the transparency standard in the courtroom, but these do not appear to be materially more difficult than those encountered in applying other standards; moreover, this standard could call attention to more important features in the ethical relationship between physician and patient. Consider the fairly typical case, in which a patient suffers harm from the occurrence of a rare but predictable complication of a procedure, and then claims that he would not have consented had he known about that risk. Under the present "enlightened" court standards, the jury would examine whether a reasonable patient would have needed to know about that risk factor prior to making a decision on the proposed intervention. Under the transparency standard, the question would instead be whether the physician thought about that risk factor as a relevant consideration prior to recommending the course of action to the patient. If the physician did seriously consider that risk factor, but failed to reveal that to the patient, he was in effect making up the patient's mind in advance about what risks were worth accepting. In that situation, the physician could easily be held liable. If, on the other hand, that risk was considered too insignificant to play a role in determining which intervention ought to be performed, the physician may still have rendered his thinking completely transparent to the patient even though that specific risk factor was not mentioned. In this circumstance, the physician would be held to have done an adequate job of disclosing information.\(^9\) A question would still exist as to whether a competent physician ought to have known about that risk factor and ought to have considered it more carefully prior to doing the procedure. But that question raises the issue of negligence, which is where such considerations properly belong, and removes the problem from the context of informed consent. Obviously, the standard of informed consent is misapplied if it is intended by itself to prevent the practice of negligent medicine.
Transparency in Medical Practice

Will adopting a legal standard like transparency change medical practice for the better? Ultimately only empirical research will answer this question. We know almost nothing about the sorts of conversations primary care physicians now have with their patients, or what would happen if these physicians routinely tried harder to share their basic thinking about therapeutic choices. In this setting it is possible to argue that the transparency standard will have deleterious effects. Perhaps the physician's basic thinking will fail to include risk issues that patients, from their perspective, would regard as substantial. Perhaps how physicians think about therapeutic choice will prove to be too idiosyncratic and variable to serve as any sort of standard. Perhaps disclosing basic thinking processes will impede rather than promote optimal patient participation in decisions.

But the transparency standard must be judged, not only against ideal medical practice, but also against the present-day standard and the message it sends to practitioners. I have argued that that message is, "You can protect yourself legally only by guessing all bad outcomes that might occur and warning each patient explicitly that he might suffer any of them." The transparency standard is an attempt to send the message, "You can protect yourself legally by conversing with your patients in a way that promotes their participation in medical decisions, and more specifically by making sure that they see the basic reasoning you used to arrive at the recommended treatment." It seems at least plausible to me that the attempt is worth making.

The reasonable person standard may still be the best way to view informed consent in highly specialized settings where a relatively small number of discrete and potentially risky procedures are the daily order of business. In primary care settings, the best ethical advice we can give physicians is to view informed consent as an ongoing process of conversation designed to maximize patient participation after adequately revealing the key facts. Because the conversation metaphor does not by itself suggest measures for later judicial review, a transparency standard, or something like it, may be a reasonable way to operationalize that concept in primary care practice. Some positive side-effects of this might be more focus on good diagnostic and therapeutic decisionmaking on the physician's part, since it will be understood that the patient will be made aware of what the physician's reasoning process has been like, and better documentation of management decisions in the patient record. If these occur, then it will be clearer that the standard of informed consent has promoted rather than impeded high quality patient care.

Acknowledgments

I plan to develop these ideas at somewhat greater length, with special emphasis on the duty to disclose remote risks, in a volume to be titled The Healer's Power (in preparation). I am grateful to Margaret Wallace and Stephen Wear for their insightful comments during the preparation of this manuscript.

References

5 Faden and Beauchamp, A History and Theory of Informed Consent, 25-49 and 114-50. I have also greatly benefited from an unpublished paper by Margaret Wallace.
6 For a specialty opinion to the contrary, see W. H. Coles et al., "Teaching Informed Consent," in Further Developments in Assessing Clinical Competence, Ian R. Hart and Ronald M. Harden, eds. (Montreal: Can-Heal Publications, 1987), 241-70. This paper is interesting in applying to specialty care a model very much like the one I propose for primary care.

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