Special Communication

Informed Consent: Law, Clinical Reality, And The Role Of The Family Physician

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Abstract: **Informed consent is typically seen as most relevant to surgical and other invasive specialties. Although family physicians perform fewer high-risk procedures, they are nonetheless extensively involved in the informed consent process because of the comprehensive and continuing nature of the family physician-patient relationship. Family physicians have a particularly important role in helping their patients to understand what diagnostic or therapeutic alternatives are available.**

Family physicians have an independent role in the informed consent process, as well as a collaborative role in the context of consultation and referral. Legal rules that require disclosure of alternatives to the patient by the treating physician are examined in the context of the family physician's role as a coordinator of patient care. Practical suggestions regarding discussion of alternatives, extent of disclosure, coordination with consulting physicians, and encouragement of patients' participation in discussions are offered. (J Am Board Fam Pract 1992; 5:207-14.)

When physicians are asked to consider informed consent and its relevance to their practices, they usually talk about written forms and high-risk procedures. Rarely do they focus on communication, patient understanding, and decision making. Their reaction is not surprising because informed consent is a product of the legal rather than the medical system, and malpractice law provides the vehicle for implementing a patient's right to be informed. The structure and operation of informed consent law encourage this constrained view. Most informed consent cases, in defining a standard for physician behavior, focus on disclosure rather than patient understanding and consent giving. In addition, because injury is a necessary ingredient in a malpractice suit, the emergence of a risk and the question of disclosure of that risk usually become the dominant issues in a case.

This legal model of physician-patient interaction more closely parallels what occurs between patients and procedure-oriented specialists than between patients and family physicians. This adherence to a procedure-oriented model exists because the law deals less with the actual process of physician-patient communication and more with the discrete, time-limited episode of the physician revealing risks of a procedure to a patient.[1] As a result, informed consent tends to be viewed as less relevant to the practice of family medicine except for the relatively infrequent instances in which the family physician performs a procedure or undertakes a treatment that is associated with significant risk. But when informed consent is viewed in its broader context as a process of physician-patient communication and decision making, then the role the family physician plays is extensive and crucial. This role extends into the surgical and other high-risk contexts when the family physician requests a consultation from or makes a referral to these specialists. Important legal questions are raised about the family physician's independent role in the informed consent process, as well as his or her collaborative role when another physician becomes involved in care of the patient.

This article argues that family physicians not only play a more important and extensive role in the informed consent process than is commonly recognized but also are often in a better position than other specialists to assist patients in making

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difficult choices. First, legal aspects of informed consent are presented with particular emphasis on the physician's obligation to discuss alternatives with the patient. Then, respective legal obligations to their patients when the family physicians refer to or consult with another physician are explored. Legal rules are compared and contrasted with ethical responsibilities of family physicians. Lastly, some practical implications for family physicians are offered.

Legal Issues

Specific rules for the law of informed consent are based on the law of the state in which a physician practices. In addition, negligence law (of which malpractice is a subset) is oriented to the individual case and is highly fact-specific. Whereas this discussion cannot provide detailed analysis and guidance, it is possible to make generalizations for the practitioner.

Numerous judicial decisions have established the generic requirements for the "elements of informed consent" that are familiar now to most physicians and institutions. They consist of the following disclosure responsibilities: (1) a description of the patient's condition and the treatment being recommended, (2) the risks of the recommended treatment (including the seriousness and probability of the risks), (3) the benefits of the recommended treatment, and (4) the discussion of alternative treatment(s) — including the alternative of no treatment — as well as the risks and benefits associated with the alternatives.

For a plaintiff to prevail in an informed consent lawsuit, he or she must persuade a jury of four key allegations: (1) the physician had a duty to disclose information, (2) the physician failed to disclose information that should have been disclosed, (3) the treatment resulted in injury to the patient, and (4) the patient would not have consented to the treatment had the patient been told the undisclosed information.

Much has been written about the standard for disclosure.[2] Approximately one-half of the states rely on customary medical practice to define what information should be disclosed to fulfill the physician's duty to the patient. The remaining states base the standard on what the reasonable person would want to know in making a health care decision. This "lay standard" removes the question of what should have been told to the patient from the realm of medical expertise and allows the jury to make this determination.

A plaintiff's argument that he or she would not have consented to treatment had he or she been adequately informed is necessary to prove causation, a requirement in all negligence cases. Most states require the plaintiff to prove that the *reasonable* person would have refused the recommended treatment. Only a few states permit plaintiffs to rely entirely on the more subjective argument that they would have refused the recommendation because of their own unique preferences. Thus, in most states, if the defense can convince the jury that most people would choose the recommended treatment even when adequately informed of risks and alternatives, the plaintiff will be unsuccessful in proving causation.

Alternative Treatments as Part of Informed Consent

Because they provide comprehensive and continuing care, family physicians have the opportunity to discuss alternatives with their patients in a timely and meaningful way. Although family physicians perform far fewer high-risk procedures than their surgical colleagues, they nevertheless have significant influence on patients' decisions because they shape their patients' knowledge and understanding of alternatives.

What does the law require with regard to disclosure of alternatives? Physicians are required to disclose alternatives that are in keeping with the standard of care.[3] Thus, alternatives that would not be considered acceptable medical practice fall outside the scope of the disclosure obligation. On the other hand, that a physician does not favor a particular alternative does not eliminate the legal obligation to discuss that alternative as long as it is a medically accepted option. Perhaps the most extreme example is the *Logan* case, which was decided by the Connecticut Supreme Court.[4] An internist recommended a closed renal biopsy to a patient and referred her to a specialist. The specialist discussed the procedure but not the alternative of an open biopsy under general anesthesia. When the patient suffered an injury that was associated with the closed biopsy procedure, she sued on a theory of lack of informed consent based on a failure to disclose the alternative. The defense argued that the informed consent obligation did not include the duty to disclose a more

hazardous procedure. But the court took the opposite view, arguing that to decide otherwise would mean that physicians were obligated to discuss only the safest procedure. An obligation to discuss only the safest procedure would obviate an important goal of informed consent, namely, to afford patients sufficient information to make an intelligent choice.

The decision of the court is troubling to a number of legal scholars because it seems to rely too much on the patient's hindsight assertion that she would have opted for the more hazardous procedure[5] and because the case affords little guidance to physicians.[6] Whether another state court would come to the same conclusion regarding more hazardous alternatives remains an open question. Other states, however, have decided cases in which the failure to discuss alternatives, thereby denying the patient a choice, was the basis for liability. Many of these cases involved an alternative that would have reduced the risk to the patient (in contrast to the *Logan* case). For example, a number of cases have held physicians liable for failure to discuss the availability of amniocentesis when the nondisclosure resulted in the birth of a child with the Down syndrome.[7,8] Some cases have held physicians liable for injury resulting from their failure to discuss a more conservative medical treatment as an alternative to a more risky and invasive diagnostic or therapeutic procedure.[9,10] In summary, a discussion of medically accepted alternatives is part of the physician's informed consent duty. Failure to discuss alternatives with the patient can result in liability on the basis of lack of informed consent.

Recommending a Particular Alternative

The underlying rationale for the informed consent obligation is enhancement of the patient's autonomy by protecting the right to choose. But it is important to recognize that the law assumes that patients want to make intelligent choices and rely heavily on their physicians for information and recommendations. The requirement that alternatives be discussed does *not* mean that physicians are expected to describe them in completely neutral terms, leaving it to patients to make choices. Indeed, the elements of informed consent listed by many courts make clear that the risks and benefits of the alternatives, as well as the physician's recommendation of a particular alternative, are important parts of the physician's disclosure obligation. As such, it is appropriate for a physician to recommend one alternative that is best suited to the patient's needs. (Of course, a patient has the legal right to reject a recommendation.) The key concern from a legal perspective is that a recommendation not be coercive because coercion would compromise the patient's right to choose. Recommendation and coercion suggest two extremes, however; the more common and difficult challenge grows out of the middle ground, where emphasis and language can strongly suggest a particular course of action to a patient. Physicians often acknowledge this reality, and psycholinguistic experts assert that there is no such thing as value-free human discourse.[11] A study by McNeil, et al.[12] demonstrated that language had a significant impact on subjects' preferences for alternative therapies. In particular, presenting medical information to the subjects in terms of survival rates, as compared with death rates, made a difference in their choices.

Courts are very unlikely to examine the subtleties of language choice because the influence of word choice, tone, and body language is too difficult to document and prove. The physician's failure to say anything, however, about a viable alternative is a more obvious elimination of the patient's options and can be viewed as a form of manipulation to gain patient compliance.[13] When the failure to discuss a viable alternative can be proved to have caused a patient's injury, courts are willing to hold physicians liable. For this reason, prudent physicians should discuss medically accepted alternatives even when they feel strongly about a recommendation.

Discussion of Alternatives in the Context of Consultation and Referral

Informed consent in the context of consultation and referral raises complex questions about the respective legal obligations of multiple physicians. Advocating for the patient's right to be informed in the context of consultation and referral is a legal development that has at times supported a very expansive view of what information must be shared. A controversial California case held the primary care physician liable for injury resulting from the physician's failure to disclose explicitly to the patient the risk of refusing to seek care from a specialist.[14] In this case the physician,

although recommending that the patient see a specialist, failed to mention concern about a possible cancer. In essence, the physician failed to describe adequately the risk of the alternative of doing nothing.

Describing alternatives to patients as part of the informed consent process is closely tied to family physicians' recommendations about consultation and referral. Because there are many conditions or illnesses that can be diagnosed or treated in more than one way, choosing one alternative over others will often determine who will provide the care to the patient — the family physician or another specialist. Examples of this abound: symptomatic treatment of suspected peptic ulcer versus endoscopy, conservative treatment of low back pain versus neurologic diagnosis or surgery, medical management of angina versus invasive diagnostic work-up. Failure to describe a viable alternative to the patient can result in liability for injury.

An additional and crucial question raised by the legal obligation to discuss alternatives is *which physician* is obligated to share this information? The general legal rule places the obligation to disclose alternatives with the physician who is to perform the procedure.[3] A number of cases illustrate the basis for this general rule. In *Halley* v. *Birbiglia*,[15] the Massachusetts Supreme Judicial Court placed the informed consent obligation squarely with the physician performing an arteriogram, rather than with the consulting neurologist, who was neither the admitting nor attending physician. Further, although the neurologist recommended the procedure, he did not order it. In the *Logan* case, discussed above, the treating urologist, rather than the referring internist, was held liable for the failure to disclose the alternative.[4] This aspect of the *Logan* case reflects the traditional rule. Some of the facts of this case concerning the respective roles of the referring and treating physicians are particularly relevant. The referring internist had described the procedure and some of its risks in general terms to the patient. Very significantly, the internist also told the patient that a more detailed explanation would be provided by the urologist. In addition, the urologist testified at the trial that he had not relied on any discussion the internist might have had with the patient.

A Maine case, *Jacobs* v. *Painter*,[16] reached the opposite conclusion for reasons that are especially illuminating. The patient's family physician sent her to a surgeon for a suspected fractured collarbone. The consulting surgeon diagnosed a dislocation of the collarbone from the sternum and discussed possible surgery but also expressed concern that these findings could indicate a possible tumor. The surgeon consultant's letter detailed these findings and opinion to the family physician and suggested further tests. Despite this advice, the family physician admitted the patient to the hospital and advised the surgeon that the patient had made the decision to have surgery. Neither physician discussed the option of foregoing surgery with the patient even though to do so was an appropriate, and possibly better, option. When the surgery was performed, the patient suffered a severe, permanent injury. The patient settled with the surgeon before trial but pursued the suit against the family physician. The Maine Supreme Court upheld the trial court's finding of liability, citing the active role the family physician had played as particularly relevant. The court devoted considerable attention to the distinction between referral and consultation, agreeing that by retaining primary responsibility for the patient (i.e., seeking consultation rather than making a referral and then making the decision to admit for surgery), the family physician also retained a duty to inform his patient about the risks of and alternatives to treatment.

It is important to emphasize that the outcome of *Jacobs* v. *Painter* is highly unusual. That is, when more than one physician is involved in the patient's care, it is normally the physician performing the treatment or procedure who has the duty of securing informed consent. The divergent outcome in *Jacobs* v. *Painter* provides an important lesson for the family physician, however. The majority opinion in the case emphasized that the family physician retained active control over the patient, largely ignoring the surgeon's recommendation for more tests. The surgeon then went ahead with surgery, also failing to inform Mrs. Jacobs adequately about the option of foregoing surgery. That the surgeon, also, was sued and settled before trial did not let the family physician off the hook. The family physician was apparently seen by the jury as sharing legal responsibility for the injury because of his active role in the decision to perform surgery.

What guidance can be derived from these cases? When the family physician's and patient's assessment and choice of alternatives involve a consulting or treating specialist, it is important to utilize fully the specialist's expertise. Translating this guideline to a strictly legal perspective, the family physician arguably ought to pass along responsibility for informing the patient to the specialist by making clear to the patient and specialist their need to have an informed consent discussion. But this legal perspective is too simplistic because it ignores the role that family physicians actually play as coordinators of their patients' care and seems to run counter to the underlying values of the discipline. The law appears to promote a limited role for the family physician; yet the "culture" of family medicine encourages an expansive role. How, then, can the "rules" associated with informed consent and liability be reconciled with the reality of practicing family medicine?

Reconciling Legal Rules with the Practice of Family Medicine

That surgeons and other procedure-oriented specialists have the greatest informed consent-based liability exposure, but tend to be the least likely to know the patient well, is an ironic comment on the gap between law and medicine. In contrast to surgeons, family physicians are particularly suited to the role of helping patients make health care decisions on the basis of meaningful communication rather than formal disclosure. Three characteristics of family medicine account for this enhanced ability to communicate: the centrality of the physician-patient relationship, comprehensive knowledge of the patient and family, and the use of time.

Family physicians have long-term relationships with many of their patients and families and understand and proceed on the principle that the relationship itself is part of the therapeutic process. Over time, physicians and patients learn things about each other. The trust that develops has an enormous impact on making health care choices. To the extent that the physician's style is collaborative, part of what is shared with the patient is the physician's thinking about treatment alternatives and selection of a particular one. Brody[17] refers to this sharing in the context of informed consent as "transparency" and advocates its adoption as the legal standard, at least for the primary care setting.

The depth of knowledge about patients and their families that family physicians develop over time also enhances physicians' abilities to engage in a process that approaches the patient autonomy value underlying the informed consent doctrine. Because family physicians provide comprehensive care to individual patients and their families, the physicians are likely to know a good deal about their patients' values and attitudes. From a legal perspective, patients need to know what their alternatives are (including risks and benefits), but they really need to know more. They need to understand how the different options affect them as individuals. They require assistance to understand the meaning of alternatives for them. Family physicians can and should play a crucial role in this interpretive process. An example of such interpretation is a discussion with a patient of the option of a computed tomographic scan that incorporates consideration of that patient's individual attribute, namely, claustrophobia. The meaning of alternatives to patients can affect their choices in ways that, to physicians, may be unacceptable. A patient's nonadherent behavior, for example, that leads to serious health risk, may be that individual's strategy for getting attention from an uncaring spouse. Unless the physician makes an effort to understand this dynamic, progress with such a patient is unlikely. The law demands only that physicians disclose alternatives, including their risks and benefits, and make a recommendation. Patients have a legal right to assent or refuse. The ethic of medicine, however, asks physicians to do more, and appropriately so, by seeking understanding and working with patients and their families to promote healthy choices.

Finally, the family physician's use of time in the care of patients has a profound impact on decision making. As physicians of first contact, often family physicians begin the process of generating alternatives for their patients to consider. Except in emergencies, patients will usually have some time to reflect on and integrate information. A patient in the family physician's office is likely to be less vulnerable and anxious than that same patient in a hospital bed on the day of surgery. The consent given just prior

to surgery is usually pro forma.[18] It is during the earlier encounter that patients are more empowered to make real choices.

When consultation or referral is added to the decision-making equation, the treating physician might assume primary responsibility for full discussion with the patient of alternatives and other elements of informed consent, with the family physician withdrawing from further discussion. As discussed above, the general legal rules are based on this construct. In practice, however, this demarcation is often not so clear-cut because patients continue to look to their family physicians for guidance. A number of examples from discussions with family physicians highlight this point. Some patients expressly rely on their family physicians for guidance in making a decision based on information provided by the consultant. In another example, family physicians can play a pivotal "quarterbacking" role by guiding their patients' decisions in the face of divergent views among multiple specialists. Finally, the simple fact that family physicians decide *whether* to recommend that their patients see another physician and *which* particular individual this physician should be has a subtle and powerful impact on choice. Selection of a conservative surgeon or a surgeon who favors a particular technique are two examples of the importance of such recommendations.

How, then, can this expansive role of the family physician in decision making be reconciled with concerns about liability exposure, particularly when high-risk procedures are being recommended by the consultant or referral physician? The family physician's goal should be to promote the patient's access to and understanding of information relevant to making a choice that best fits that patient. The treating physician should be explicitly relied upon as the primary source for technical information about risks, benefits, and alternatives. The family physician should collaborate closely with the treating physician (as well as the patient) to integrate what each knows best — knowledge of the patient with knowledge of the condition and ways to treat it. The problem in *Jacobs* v. *Painter*[16] was the family physician's emphasis on a particular course of action at the expense of attending to the patient's need for information and understanding.

Practical Implications

A number of practical lessons can be drawn from an understanding of the law of informed consent, and how the law can be incorporated into the goals of family medicine.

Commitment to Discussing Alternatives

Because patient choice is the central message of informed consent law, the discussion of alternatives is a crucial part of the process, particularly when liability exposure increases because some or all of the options involve serious risk. The physician's commitment to a particular alternative (in the form of a recommendation) does not supplant the need to review other options, and we know patients will sometimes exercise an option the physician does not favor. Making choices for the patient, however, through silence about alternatives is legally risky and violates the patient's trust in the physician. There are many historical reasons why physicians have resisted telling patients about alternatives. A troubling, more recent reason can be the desire in some situations to avoid offering alternatives that are viewed as too costly. This heightened pressure of financially based motivations for not sharing information about alternatives adds a new layer of concern among physicians and their patients and increases liability exposure. Although discussion of financial motivation as a factor in informed consent is beyond the scope of this article, its relevance to the sharing of information with patients must be acknowledged and addressed.[19-22]

How Extensive Should Disclosure Be?

Detailed discussions of alternatives in every patient encounter are unrealistic and unnecessary. Many treatments undertaken by family physicians involve negligible risks. Further, there are often only two viable alternatives — one particular treatment or doing nothing — that are sufficiently common and well understood by most patients and require little explanation. There are instances, however, where family physicians should discuss alternatives more carefully and comprehensively. Two factors should be considered: (1) how risky is an alternative, and (2) how elective is the recommended alternative? A useful guideline, which is based on both common sense and analysis of case law, calls for fuller, more thorough disclosure in situations where the alter-

natives are more or less equivalent, especially when the alternative of doing nothing is a reasonable alternative from a medical standpoint. Put another way, the more elective a risky treatment, the more thorough the informed consent process should be.

Knowing the Alternatives

While it may be obvious that physicians need to know what the alternatives are to be able to share the information with their patients, the continual development of new diagnostic and therapeutic alternatives poses a significant challenge. This clearly has implications for continuing medical education (CME); family physicians should plan their CME curricula to include presentations on the relative utility of various alternatives in diagnosis and treatment. In addition, inevitably there will be procedures the primary care physician knows little or nothing about. Knowing what one does not know and explicitly relying on the consultant for full discussion of risks and benefits of various alternatives are prudent forms of liability risk reduction and, more importantly, good medicine.

Coordinate Carefully with the Consultant or Treating Physician

The family physician's role as a coordinator of the patient's care should include coordination of efforts to meet the patient's information needs. Thus, when a patient is receiving treatment from another physician but is asking the family physician for more information or is expressing confusion or doubt, the intervention should be aimed at achieving patient understanding. This can be done, for example, by having the consultant clarify or review information and having the patient tell the physician what the patient understands about the treatment. In effect, the family physician may need to press the consultant for a more thorough discussion with the patient and may need to check back with the patient to be sure the patient understands the information.

Set a Tone of Openness with the Patient

The law of informed consent requires physicians to disclose information. No parallel legal obligation is placed on patients to ask questions. Thus, the patient's failure to inquire in no way mitigates the physician's legal duty. But physicians do want their patients to inquire because that tells physicians something about their patients' thinking, concerns, and level of understanding. A physician's interactional style has enormous impact on whether patients will ask. Encouraging patients to ask questions of oneself and of the consultant is an important part of the family physician's role as patient advocate. From a legal perspective, it also communicates that the consultant is a key source of further, more detailed information concerning options.

Conclusion

The family physician's role in the informed consent process is not limited to the relatively few occasions when risky procedures or therapies are employed in the primary care context. When informed consent is construed more broadly to incorporate the process of physician-patient decision making, the family physician exercises enormous influence on how patients actually make decisions. The goal of family medicine to provide comprehensive and continuing care to the patient can be reconciled with the rules of informed consent law by making patient understanding and informed choice a focus of patient advocacy.

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