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8 ways to improve the informed consent process

These practical suggestions can strengthen your rapport with patients and help ensure your professional counsel is complete and documented.

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PRACTICE RECOMMENDATION

- *Let patients know that informed consent is an interactive process leading to mutual agreement, rather than a formality and forced choice.* (C)
- *Present all treatment options even if a patient's insurance does not cover them all.* (C)
- *Discuss the advantages, disadvantages, and limitations of the tests you are ordering or recommending—particularly nonroutine lab work.* (C)

Strength of recommendation (SOR)

- (A) Good-quality patient-oriented evidence
- (B) Inconsistent or limited-quality patient-oriented evidence
- (C) Consensus, usual practice, opinion, disease-oriented evidence, case series

Once viewed as simply a legal preamble to treatment, informed consent today encompasses much more. An essential part of the ethical practice of medicine,[1] it is also an opportunity to strengthen the doctor-patient relationship. Effective informed consent embodies the shift in primary care medicine to guide rather than dictate an individual's health care decisions, often termed *shared decision making*.[2] Furthermore, informed consent is increasingly relevant in today's evolving legislative expectations[3] and health care initiatives.[4] For risk management, the physician has more direct control over the process of informed consent than most other areas pertaining to medical negligence. Thus, incorporating improvements to the process of informed consent is time well invested.

In this article I will discuss the components of informed consent and recommend practical steps to its effective delivery for mentally competent adult patients.

What informed consent requires

In the office setting, obtain informed consent before you start treatments or procedures, prescribe medications, or order most diagnostic tests. Informed consent requires that the patient understands the following:

- the *material* risks and benefits of a proposed treatment
- the reasonable alternative treatments
- the consequences of no treatment.

Physicians are not expected to disclose every risk to a patient. However, both common risks and uncommon but serious risks are considered material.[5] In the extreme, a mentally competent patient may refuse lifesaving therapy if she or he understands the risk of doing so.[6]

The legal criteria that determine whether a physician satisfied the standard of care for informed consent vary from state to state. Some states test the physician's conduct against what a "reasonable physician" should have disclosed. Other

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states apply what a "reasonable patient" would want to know, and some apply a combination of both. As such, legal cases provide little direction to physicians on how to decide what is material.[7]

Patients generally take 1 of 2 approaches when pursuing action against a physician that is related to informed consent.[8]

The first, and most common, cause of action is *negligence*. This occurs when a patient claims that the physician's disclosures in the consent process were inadequate. The patient is then required to prove the elements of negligence: breach of standard of care, causation, and damages.

The second potential cause of action is *battery*, which is an unlawful touching. Proving battery is simpler because there are fewer elements to the claim. If a procedure or examination took place without the patient's consent or was beyond the scope of the consent given, a battery action is possible, whether or not the outcome of a treatment was beneficial to the patient.

Now, on to the steps that can help improve the informed consent process.

1 Work on your rapport

The importance of good rapport between the patient and physician cannot be overemphasized. The level of rapport is a better predictor of the risk of litigation than the actual content of any particular discussion.[9]

A few tips to improve rapport. If you approach informed consent merely as a legal technicality, the tone you take in the discussion may reflect that attitude. Instead, enter into a consent discussion in such a manner that the patient understands it is an interactive process leading to mutual agreement rather than a formality. Should an adverse outcome occur, a patient who recalls feeling pressured may claim that not all the key information was presented. Don't be dogmatic in making recommendations; scientific evidence and medical opinion can change with time. Hormone replacement therapy and cyclooxygenase-2 inhibitors are current examples that demonstrate the importance of allowing the patient to make a decision about therapy.

Effective communication reduces the likelihood of litigation.[7] One model of more effective communication is the "teach back" approach,[4] in which you identify the principal messages of the discussion and ask the patient to paraphrase them. This approach emphasizes the use of simple, clear language in layman's terms, relying on your ability to explain rather than the patient's ability to comprehend. Questions such as "Do you have any questions?" or "Do you understand?" are less effective than saying "I want to be sure we have the same understanding" or asking "Can you tell me in your own words?"[4] (See "Putting informed consent principles into practice" by going to jfponline.com and scrolling to the end of this article.)

2 Discuss all treatment options—regardless of insurance coverage

Determining what should be disclosed as a *material* risk in the consent process can be challenging. It's imperative to be familiar with the medical literature as well as the important risks and benefits of treatments. However, use statistics judiciously and meaningfully. Overusing statistical data can confuse and even alienate some patients. The goal is to achieve an understanding about whether a risk is relatively common or relatively rare, but serious.

Present all treatment options regardless of whether the patient's insurance covers all of them.[1] Consider a patient's unique financial situation in the shared decision-making process.

Exhaustive lists of potential risks are impractical and, more important, are ineffective, as the risks have not been put into context for the patient. A list of routine risks is a good starting point and provides structure to the discussion. Then, by taking the patient's point of view, identify important, patient-specific risks. Customizing the discussion for each individual is the key principle in the duty to inform.[10] Common issues include how a side effect or adverse outcome might affect a person's occupation, fertility, sexual function, appearance, etc. Other issues include the pain incurred, degree of rehabilitation, restrictions on lifestyle, etc.

3 Use the ABCDEF mnemonic

The following mnemonic is useful for guiding and documenting your discussion with

the patient:

Alternative therapies available
Benefits of the therapy proposed
Common but not devastating risks
Devastating but not common risks
Extra considerations specific to this patient
Facial expressions, body language, and questions.

4 Decide how much medication information the patient needs

The learned intermediary doctrine is a legal concept whereby a pharmaceutical company is deemed to have discharged its responsibility to patients (in whole or in part) for side effects they have disclosed to physicians, commonly through the product monograph.[11] To limit risks, it is prudent to use a limited number of first-line drugs in each class, rather than a lot of samples and new drugs, until you review monographs and the literature. As a final check on your duty to inform, encourage a patient to discuss with his or her pharmacist the drug you have prescribed, to further reduce inadvertent errors and side effects.

Decide how much information the patient needs. A recital of every risk in taking an antibiotic is untenable. However, certain drugs require more detailed discussion. Oral contraceptives, analgesics, and cardiovascular drugs are a few classes of medications that have infrequent, but serious, side effects. Generally, these risks are so devastating (eg, stroke associated with oral contraceptives) that lawsuits are common. Important information that is not directly health related includes occupational or driving limitations while a patient is taking a drug that alters mental status.

Ask patients to tell you about any supplements or alternative therapies they use. Many complementary treatments can have an effect on medical therapy.

If a patient asks about alternative medicine, disclose your level of training in the area and discuss candidly any known related medical issues. For example, a patient with neck pain may ask for an opinion about, or a referral for, chiropractic care. Discuss known risks, such as vertebral artery dissection, and be frank when you cannot endorse the therapy for lack of training or scientific evidence.

Discussing enrollment in a medication research trial increases a physician's duties of disclosure before a patient decides to participate.[12] You must convey that the therapy has unknown risks and may turn out to be harmful. Also, the sponsor of the study, the institutional review board, and government agencies (eg, the US Food and Drug Administration and the Department of Health and Human Services) may require discussion and documentation of specific risks.

5 Discuss how test results will be communicated

Laboratory or radiology investigations and their results introduce a unique set of issues. Particularly for nonroutine lab work, it's prudent to discuss the advantages, disadvantages, and limitations of the test being ordered or recommended. These discussions can become the subject of suits when a patient receives a diagnosis and wonders in hindsight if his or her doctor missed the true diagnosis or should have been more aggressive in the investigation. Consider inviting your local laboratory or radiology group to make a presentation to keep you up-to-date on available options.

Obtaining informed consent provides a helpful segue to discussing how test results can best be shared with the patient. An all-too-common problem is that test results can become lost or misfiled. Describe your office policy on calling patients with results, and think about when it might be advisable for the patient to follow up with the office, to reduce error and liability—eg, cancer screenings, Pap tests, and biopsy results.

6 Keep a record of referrals

A patient generally has the right to refuse specialty treatment[13] or referral to a specialist,[14] once informed of the risks of delay or lack of treatment after making such a decision. If a patient still refuses referral, document the decision in case it results in a delayed diagnosis or an adverse outcome.

Generally, the specialist has the duty to inform the patient of the risks and benefits of the specialty treatment. However, it has been

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held that a primary care physician still bears some responsibility to assure the welfare of the patient in all phases of treatment.[15] Thus, it is prudent to ensure that patients have not been lost to specialty follow-up. In a busy practice it is often difficult, of course, to keep track of the status of all referrals, and specialty offices differ in efforts to keep primary care physicians informed. Use the informed consent process to raise and discuss such issues. Encourage your patients to notify you or your staff if they have experienced a delay in care with a specialist you referred them to.

7 Avoid making guarantees about procedures

All procedures, including associated anesthesia, require a discussion of risks and benefits. If appropriate, also discuss available alternative procedures and your reasons for not recommending them. For example, a breast lump can be imaged, aspirated in the office, or surgically excised. All options need to be discussed and the course of action mutually agreed upon. A patient may not necessarily want the least invasive option.

Avoid assurances or guarantees regarding a specific outcome. Such guarantees can be the impetus for legal action (*breach of warranty claim*) should the promised outcome fail to occur. Exercise caution, for example, in explaining outcomes and risks for cosmetic procedures. If a patient has a complicated problem or unrealistically high expectations, consider a referral for a second opinion or for management by a specialist.

If a patient refuses referral, document the decision in case it results in a delayed diagnosis or an adverse outcome.

8 Document, document, document

Documentation is a necessary, final step. It records the process that is vital to good patient care and it may be the only proof that a discussion took place. Legal case opinions shed little light on what represents adequate documentation. Implement a record-keeping strategy that suits your practice setting and style. Products or guides for this purpose are available commercially or through medical societies, malpractice carriers, legislative initiatives, and special interest groups.[16] If you use a preset consent form, make sure it is not intimidating or confusing. Initiatives to improve health literacy suggest that literature, to be effective, should be written at the fifth grade level.[17]

Forms with boilerplate language that simply require a signature are inferior to documents that give details of the meaningful discussion that took place. Drawings or notes stating which family members were present or what questions were asked can demonstrate the particulars of the discussion for a specific patient. It is also useful to document secondary resources you used, suggested, or gave to the patient, such as models, diagrams, pamphlets, CDs, and DVDs. JFP

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References

1. American Medical Association (AMA). *Health and Ethics Policies of the AMA House of Delegates* (Policy H-140.989 and H-160.998). Available at: http://www.ama-assn.org/ad-com/polfind/Hlth-Ethics.pdf. Accessed June 16, 1010.
2. Frosch DL, Kaplan RM. Shared decision making in clinical medicine: past research and future directions. *Am J Prev Med*. 1999;17:285-294.
3. For example, The Patient Self-Determination Act 42 U.S.C.§§1395cc(a) et seq., as amended (2003).
4. National Quality Forum. *Implementing a National Voluntary Consensus Standard for Informed Consent: A Users Guide for Healthcare Professionals*. Washington, DC: National Quality Forum; 2005:13, 15, 27.
5. *Salgo v Stanford University Board of Trustees*, 154 Cal. App. 2d 560, 317 P. 2d 170 (1957).
6. *Cruzan v Director, Missouri Department of Health*, 497 U.S. 261 (1990).
7. Berg JW, Appelbaum PS, Lidz CW, et al. *Informed Consent Legal Theory and Clinical Practice*. 2nd ed. New York, NY: Oxford University Press; 2001:46-55.
8. 61 Am Jur 2d Physicians and Surgeons §151-152, pp 274-275.
9. Levinson W, Roter DL, Mullooly JP, et al. Physician-patient communication: the relationship with malpractice claims among primary care physicians and surgeons. *JAMA*. 1997;277:553-559.
10. Rozovsky FA. *Consent to Treatment: A Practical Guide*. 4th ed. Frederick, Md: Aspen Publishers; 2007:8-11.
11. *Martin v Hacker*, 83 NY 2d 1, N.E. 2d 1308 (1993).
12. *Moore v The Regents of the University of California*, 793 P.2d 479 (Cal 1990).
13. *Moore v Preventative Medicine Group, Inc.*, 178 Cal. App 3d 728, 223 Cal Rptr. 859 (Cal Ct. App. 1986).
14. *Truman v Thomas*, 27 Cal. 3d 285, 611 P. 2d 902, 165 Cal. Rptr. 308 (1980).
15. *Prooth v Walsh*, 432 N.Y.S. 2d 663 (Sup Ct. 1980).
16. Landro L. Consent forms that patients can understand. *The Wall Street Journal*. February 8, 2008. Available at: http://online.wsj.com/article/SB120224055435844931.html. Accessed February 10, 2008.
17. Safeer RS, Keenan ES. Health literacy: the gap between physicians and patients. *Am Fam Phys*. 2005;72:463-468.

Putting informed consent principles into practice

Dr. B holds a busy walk-in clinic after-hours in her office. She sees Harry, a 27-year-old man for the first time. Harry is uninsured and presents with fatigue and a 3-month cough. He is a non-smoker and believes he is tired because he has been working 2 jobs and has had 2 severe viral illnesses in the last few months. Many of his symptoms suggest reactive airways and post-viral cough. However, Dr. B is concerned about other diseases based on Harry's general appearance, such as Hodgkin's lymphoma. Dr. B is also anxious, because one of the clinic doctors has recently been sued for missing lung cancer in a young man. She wonders how to best proceed with treatment to suit Harry's needs and avoid unnecessary liability.

Dr. B does not have the benefit of a long-term relationship with Harry and may feel inclined to suggest an aggressive investigation to avoid missing disease and subsequent litigation. However, establishing good rapport and communicating effectively would better serve them both. Dr. B's challenge is to ensure that Harry understands that he most likely has a simple disease process, but that they need to consider more serious possibilities. Harry must also understand the consequences of poor follow-up and delayed investigation. Dr. B should explain that deciding how to proceed will be a shared process that leads to a medically sound and financially practical option.

As an example, Dr. B could suggest a course of therapy for reactive airways, such as a beta-2 agonist and inhaled corticosteroid. She should describe both the common and the serious side effects for each. She should also counsel Harry to go over his medications with the pharmacist.

Dr. B may advise a screening chest x-ray now or offer close follow-up and a trial of inhalers for a reasonable period. She should explain that a chest x-ray has diagnostic limitations and that Harry may need further investigations, such as a chest CT or referral. At this point, Harry is ready to share in the decision on how to proceed.

At the end of this discussion, Harry should be asked to "teach back" his understanding of the treatment plan. Dr. B should then document the salient points (at minimum: "cost concerns," "follow-up necessary to rule out serious pathology," "risks and benefits of medications discussed and advised to also discuss with pharmacist," "chest x-ray advised and discussed other investigation options," and "teach-back method used to confirm plan").