

Informed Consent and The Family Physician

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Informed consent, regardless of patient recall, is required in increasing detail. The family physician must obtain consent from every patient for every procedure except for a few clearly defined areas: "Emergency," "Waiver," "Therapeutic Privilege," "Immaterial Risks," and "Generally Known Risks." Because courts have adopted the "reasonable patient" standard of disclosure, suits can be won without expert testimony. The elements of informed consent require explaining the nature of the procedure, the consequences that will probably occur, the material risks that may occur, alternatives available, and problems in recuperation. Consent, like any contract, is a meeting of the minds and the physician has an obligation to himself to document that agreement.

The doctrine of informed consent is becoming the law of the land. Early on John Stuart Mill asserted the foundation of self-determination which undergirds the rule of informed consent.

The only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not a sufficient warrant.¹

Approximately 20 states have informed consent doctrine statutes and many more recognize and enforce the common law principle without a specific statute. The famed New York Supreme Court Justice Cardozo affirmed,

Every human being of adult years and sound mind has a right to determine what shall be done with his own body.²

In 1960, in an early landmark case of informed consent, a patient suffered skin breakdown from

radiation treatments for breast cancer. The Kansas Court stated,

A man is the master of his own body and he may expressly prohibit the performance of life saving surgery or other medical treatment.³

Notable organizations have adopted Bills of Patient's Rights which further legitimize this doctrine's place in medical practice.

The patient has the right to receive from his physician information necessary to give informed consent prior to the start of any procedure and/or treatment. Except in emergencies. . .⁴

The patient has the right to reasonably informed participation in decisions involving his health care. To the degree possible, this should be based on a clear, concise explanation of his condition and of all proposed technical *procedures*, including the possibilities of any *risk* of mortality or serious side effects, problems related to *recuperation*, and *probability* of success. The patient should not be subject to any procedure without his voluntary, competent, and understanding consent or that of his legally authorized representative. Where medically significant *alternatives* for care or treatment exist, the patient shall be so informed.⁵ (emphasis supplied)

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The patient has a right to full information on his diagnosis, treatment, and prognosis in terms he can understand. . . . The patient has the right to control his body and life. This includes the patient's right to refuse treatment to the extent permitted by law, to be informed of the medical consequences of his action, and to leave the hospital when he decides to do so.⁶

The fear of many physicians is that patients will refuse a treatment or procedure when it is explained to them with the attendant risks. On the other hand, many law suits are the result of inadequate information being given and thus *uninformed* consent being obtained. Informed consent requirements are supposed to give the patient the information and power to reject the physician's recommendation before the procedure is carried out. Such information is well received.⁷ One study of 100 patients for peroral endoscopy found 64 percent of the patients stated that full disclosure aided them in making a decision to accept or reject the procedure.⁸ In that study, 34 percent stated that full disclosure increased their apprehensions and all of these consented. Another 232-patient study showed that 89 percent of the patients found the information given for informed consent to be helpful in making their decision about consent.⁹

Family physicians need to differentiate two categories of informed consent: express and implied. This is not the same as oral and written consent, both of which are express, the latter being documented. This article will elaborate the elements of a properly collected informed consent. The nature of the risks which must be disclosed will be examined and examples of application given. Therapeutic privilege has a narrow application and physicians must document properly the basis for it.

Legal Bases for Suits

Originally the lack of informed consent could result in a charge of assault² and battery, as in the case where the patient agreed to a procedure on one ear and both ears were treated.¹⁰ Battery is an intentional touching of another's person without authorization. Today informed consent suits for battery are reserved for situations wherein there was a completely unauthorized procedure¹¹ or where there is an obvious discrepancy between what was told and done by the physician.¹² In such a situation there is no consent at all.

Negligence is the cause of action now accepted for almost all of the lack of informed consent cases. In 1957, the California Supreme Court judged a physician negligent in withholding the one percent risk of paralysis from a patient consenting to undergo aortography.¹³ This procedure was not performed negligently, but rather the physician was negligent in his preliminary discussions with the patient.¹⁴

Liability may apply in the case if a different part of the body was injured for reasons other than negligence and the patient was not informed of this possibility. In the *Fogal* case,¹⁵ the physician did not explain the dangers of a hypothermia blanket. The use of it resulted in necrosis of skin tissue other than at the site of the procedure.

What Is Informed Consent?

There are four elements of informed consent, the third of which is the battleground for practicing physicians and attorneys:

1. Patient is competent (age and mental capacity)
2. The consent is voluntary
3. The information given is sufficient
4. The information is understood by the patient

The sufficiency of information passed from physician to patient is the struggle between the patient's right to self-determination and the physician's duty not to generate a medically significant anxiety in the patient. In short, they have been called the "risks and alternatives" or the "options and perils." More clearly, the physician should address:

- A. The nature of the procedure
- B. Probable consequences (desirable and undesirable results that *will* probably occur)
- C. Possible material risks that *may* occur (a combination of seriousness or incidence rate)
- D. Alternatives with their probable consequences and possible risks
- E. Problems of recuperation¹⁶

It is important to realize that informed consent is an agreement between physician and patient, so much so that a precedent setting Pennsylvania decision referred to it as a contract.¹⁷ In the case of informed consent, the contract or consent is not synonymous with the documentation of the informed consent.¹⁸ The agreement comes during a conversation and "virtually the only way to obtain informed consent is through a conversation. . . the over-riding importance of a conversation cannot

be minimized."¹⁸ A signed written form alone is not enough.¹⁹ The advantage of having a piece of paper is merely to corroborate the physician's testimony that *something* was said. The consent *form* will rarely address itself to the real issue at hand which is whether or not the physician and patient discussed the consequence which occurred. There must be a meeting of minds between physician and patient. Thus, battery was successfully charged by a patient who signed a consent for "hip prosthesis on right side." The patient thought it would be a total replacement. The physician thought to and did perform a partial replacement, leaving the original socket.²⁰ Physicians have won malpractice actions for lack of informed consent when there has been no writing at all.²¹

Scope of Disclosure

In discussing the probable consequences, possible risks, alternatives, and recuperation period, most physicians are concerned about the limits of disclosure. There are basically two standards of disclosure in effect in the various states. The first is the *reasonable physician standard* in which the physician is required to communicate to the patient the amount of information that is given by other physicians. This amount is established by expert testimony.²²⁻²⁵ This is sometimes called the objective test and used to be the rule in the majority of states.^{26,27} It still is the law in many states.

The *reasonable patient standard* which has now become the majority rule,²⁸ requires the physician to communicate that amount of information which a reasonable patient in that situation would need to make his or her decision. Courts have required that the patient be told the risks "material to a patient's decision" to consent or not,¹⁶ and that the determinative factor is "the patient's informational needs."²⁹ The patient must prove that with that material knowledge it is reasonable to assume he would have not consented.

Materiality of Risk

Material facts combine a minimal disclosure of both the severity of the danger and its likelihood or degree of incidence.^{29,30} Courts have stated broadly that the physician need "not give a mini-course in medical science."^{16,31}

Courts have failed to speak to the factors which together comprise materiality, but some decisions

are revealing that if the complication is severe or if the degree of incidence is high, then the physician must communicate that before treatment. In the case of paralysis, the courts have held that it must be made known in thyroidectomies (vocal cord paralysis),^{21,32} and laminectomies (one percent paraplegia),³³ and in shoulder manipulations (five percent arm paralysis from brachial plexus stretch).³⁴ A physician should have advised a patient of an only 50 percent success rate in dermabrasion where hyperpigmentation resulted instead.³¹

A physician need not relate minor risks inherent in common procedures. A tubal ligation patient was not told of the two percent chance of incomplete sterilization. The court at first affirmed the physician,³⁵ but since the state had adopted the "reasonable patient" rule, the case was reversed for a new trial³⁶ in which a jury will decide whether a reasonable patient requires such knowledge. Physicians have had to pay child rearing expenses^{37,38} for failed vasectomies, but these cases were the performance of negligent surgery, *not* negligent informed consent.

The California Appellate Court affirmed the physician who advised his coronary arteriography patient of the possibility of "death or serious diseases."³⁹ However, just stating death, numbness, and heart attack was not reasonable disclosure prior to carotid body surgery which carried a 15 percent risk of increased blood pressure.⁴⁰

When Is Informed Consent Not Required?

There are five defenses to a lack of informed consent by a physician to a patient. It is essential to record in writing the facts underlying the physician's conclusion that one of these areas is applicable.

1. Risks Generally Known

When a relatively minor risk is also inherent in a procedure and is common knowledge to a reasonable patient, then the risk need not be disclosed.¹⁶ Thus, in the case of blood transfusion the .013 chance of hepatitis did not have to be disclosed according to a federal court in Tennessee.⁴¹

2. Patient Asks Not To Be Told

If the patient has the right to know the procedure's nature, risks, and alternatives, then the patient has the right to waive the right.¹⁶

3. Emergency

An emergency is a condition which constitutes an immediate danger to the life or health of the patient and which precludes the taking of the time to obtain a consent from the patient or next of kin.^{42,43} The patient record should indicate that a reasonable effort was made to obtain a consent, in light of the time available and the materiality (severity and likelihood) of the risks of the procedure.

4. Not a Reasonable Need for Patient To Know

This is the standard of disclosure problem. In the more demanding jurisdictions (now the majority), the minimum disclosure is the need of a "reasonable patient," not that of a "reasonable physician" or what physicians locally or nationally are telling their patients. This could include low incidence, non-serious complications and requires disclosure of serious or high incidence complications.

5. Therapeutic Privilege

When in the physician's opinion disclosure would complicate or hinder treatment, cause psychological harm, or upset the patient so much as to be unable to make a decision, then consent need not be obtained from the patient.⁴⁴ The fact that disclosure might create anxiety in a patient is *not* sufficient to warrant application of this exception.

In *Nishi vs Hartwell*,⁴⁵ physicians testified: This man was well educated, a fine man, but in addition he was very frightened about his condition. He was apprehensive, and this actually guided our hand in much of what we did because if a man has a serious heart disease, with hypertension, and you thereupon frighten him further, you have a problem which you have created.

In deciding to perform a thoracic aortography, the physician testified:

... if I had sat down with Dr. Nishi and said, 'We are about to inject something into you which has a remote chance of causing you to be paralyzed, you may get an immediate reaction which will cost you your life,' if I had said these things to Dr. Nishi, I think it would have been a terrible mistake.⁴⁵

The Hawaii Supreme Court decided that Dr. Hartwell had come within the "therapeutic privilege" defined in 1960 by the Kansas Court in *Nathan vs Kline*:

where the disclosure... would seriously jeopardize the recovery of an unstable, temperamental, or severely depressed person.⁴⁶

Before opting to treat a patient under the therapeutic privilege, a physician should obtain consultation with another physician to make an independent determination that there is a real basis to rely on this exception. He should document exactly what risks are being withheld from the patient's knowledge and why. The physician is then best advised to disclose those risks to the appropriate next of kin and to document that fact also. This communication with the next of kin is not thereby asking for their consent in the stead of the patient, as one would for an incompetent.

Other Types of Consent

There are three areas in which consent to a treatment or procedure is required but it is not expressed by the patient: implied consent, incompetents, and minors.

1. Implied Consent

Implied consent is given by the actions of the patient who can reasonably infer from the circumstances the nature of the procedure about to occur and its attendant consequences, risks, and other alternatives. This used to be a widely applicable doctrine before the doctrine of informed consent became so rigorous. The classic case was a ship passenger lining up with others to receive a vaccination.⁴⁷

One might think the patient giving implied consent to be an exception to informed consent patients and need not be informed. This is *not* the case and the patient giving implied consent needs to be informed. All the risks are inevitably *not* known generally to an average, reasonable patient. The individual patient must be given actual knowledge of the risks not generally known.

2. Incompetents

In the case of providing medical treatment for incompetents, one of the four basic elements of informed consent is missing: competent, voluntary, sufficient information given and comprehended. It is not a case for "therapeutic privilege" where a less than totally informed consent is necessary. Rather, a fully informed consent must be provided by a third party. The tests for

competency to consent to treatment are that the patient understand the nature of the procedure or treatment as well as the risks, benefits, and alternatives.⁴⁸

If the patient has not been found legally incompetent or institutionalized, the next of kin or a guardian temporarily appointed for this purpose signs the consent. If there is any question about the competency, the patient should also sign the consent and if he refuses, then in the non-emergency situation, a temporary guardian may be applied for by the family through the court.

The physician who refuses treatment to an incompetent patient is in a dilemma as he may be liable in negligence for not providing medical care.⁴⁹ The physician is required to take reasonable steps to obtain some legally valid authorization. To do otherwise may introduce the issue of abandonment.

3. Minors

For the purpose of consenting to medical treatment, the age of consent depends on state laws, but since the passage of the 26th Amendment it is never above the age of 18 years. Some states reduce to 14 years the age of consent to medical treatment. Physicians treating persons below that age must have the consent of their parents, unless the facts of the given case fall into the standard exceptions or one of the following exceptions which vary according to state law.⁵⁰ In these cases that follow, the minor is treated like an adult and can give his own consent:

1. Married minors
2. High school graduates⁵¹
3. Minor who has been pregnant
4. Diagnosis and treatment for venereal disease and pregnancy
5. Minor parent can give consent for own minor child without patient's grandparental consent
6. Emancipated minors, which generally refers to self-supporting persons to whom the parents have voluntarily or involuntarily surrendered their parental duties

Most states have a statute which protects the physician in the case of a minor who professes to be an adult but is not,⁵² as long as the physician relied in good faith upon the representations of the minor.

In the situations where a minor is able to give consent as if he were an adult, the physician *can-*

not then apply the "therapeutic privilege" exception to the need for informed consent. Courts have decided this as a matter of public policy to avoid potential abuse of the privilege. Further, as a matter of confidentiality, the minor being treated under his own consent must be billed directly, not through his parents.

When parents object to advisable treatment in the non-emergency situation, then the physician may refer the matter to the Children's Social Service Agency which will petition the appropriate court. In an emergency, physicians may treat without parental consent,⁵³ though there are no cases stating the physician may treat *in spite of* parental refusal to give consent. The minor child who has the right to consent as an adult also has the right to refuse consent. However, the minor child who does not have the right to consent may have the right to refuse or withdraw consent.

Informed Consent in Family Practice

Areas of Implied Consent

Most of the cases which a family physician sees can be properly handled by means of the doctrine of implied consent, provided the physician makes sure the patient has the necessary background information to properly, "legally" assent by compliance. The general public knows, for example, all there is necessary to know about many of the diagnostic "touchings" which the physician may do in a general physical examination. It is necessary that the physician make sure of patient awareness by stating expressly the consequences, dangers, and/or alternatives which are not generally known by the "reasonable patient." In particular, in prescribing most medications, the physician need not obtain an express verbal or written contract with the patient but he must explain by way of warning the probable and improbable side effects. In the case of undesirable side effects (risks), the physician should give an idea of seriousness and incidence. The physician should also state the alternatives.

So too with laryngoscopic and pelvic examinations, the physician explains procedures just ahead of their execution. He is laying the foundation for implied consent. Finally, the physician must explain to the patient the responsibilities which are to become the patient's. Thus, in sutur-

ing, although the alternatives may be obvious, the consequences of patient return, suture removal, and wound care must be made clear. This all need not be done in a framework of asking permission or bargaining. It is a flow of information. Authorization comes by compliance.

Areas of Express Consent

Some areas of family practice are so significantly risk laden either in terms of seriousness or incidence that it is the better practice to formalize the transfer of information and/or the patient's consent. In these cases, it may not be appropriate to receive a written informed consent, but it is definitely appropriate to receive an express and informed consent. In prescribing contraceptive pills, a physician was held negligent for not advising the patient about the abnormal blood clotting possibilities.⁵⁴ Similarly, these entries should be made with a prescription for diethylstilbestrol. The chart must, *at a minimum*, reflect that the patient received information, what the categories of information were, and that the patient consented.

Intrauterine device insertions should be preceded by the physician providing a booklet (put out by some drug companies) which explains the consequences, risks, and alternatives. The patient record should reflect the booklet being given at the previous visit. On the date of the visit there should be a conversation about the consequences, risks, and alternatives. The record should reflect not merely "pros and cons discussed," but more specifically "consequences, risks, and alternatives discussed. Patient consents to IUD. IUD inserted." One physician failed to inform the patient of the risks of an IUD. The patient contracted pelvic inflammatory disease and became sterile. Although the court found the patient 40 percent contributorily negligent, the award was \$80,000 to the patient.⁵⁵ In that case, the physician also failed to perform a physical examination and to treat the pelvic inflammatory disease adequately.

Informed Consent for Referred Patients

When patients are referred, the specialists or subspecialists must personally obtain the informed consent of the patient. The physician who performs a procedure or treatment is bound by the terms of the consent given by the patient to the giver of information. Further, when one physician

gives information and another does the procedure, there is no mutuality of minds, because the details the patient relies upon and the specificity of his consent get diluted by the additional link in communication.

Thus, in a referral for aortography, the radiologist is responsible to provide information and receive consent, as is the internist for informed consent for gastroscopy. The information which the referring family physician provides should not be viewed as and is not that information which binds patient and physician in the consent later given to the specialist to proceed. By providing such information, the family physician is doing important work to educate the patient and to alleviate fears, not as a prelude to receiving permission for someone else to act upon the patient's body. The family physician is not doing the informing in a referral on behalf of the consultant.

Tools to Obtain and/or Document Informed Consent

Any documentation other than a tape recording is merely evidence that a competent patient was informed, comprehended, and voluntarily consented to a procedure or treatment. Postoperatively, patients rarely recall the information they received preoperatively.^{56,57} Thus, documentation is crucial. There are basically two emphases the physician can express: to protect himself or to educate the patient.

There are three ways for physicians to protect themselves. First, the physician may make a note in the chart that consequences, risks, and alternatives were discussed. Secondly, a form stating the same may be signed by the patient. In both cases, should legal dispute arise, testimony will be required. Thirdly, the physician can have the patient sign a preprinted form which for a given treatment itemizes all the consequences, risks, and alternatives. This could be done in IUD insertions and for the prescribing of potentially toxic cardiovascular or renal drugs.

There are three ways the family physician might emphasize patient education. First, the physician may provide an informational booklet or sheet drawn up by the physician with a signature line over a statement which incorporates the fact that the patient had the opportunity to read the sheet. Written transfer of information emphasizes patient responsibility for treatment. Secondly, the physi-

cian may provide a two-part consent form, the first part setting out the specific treatment, consequences, risks, and alternatives. This should expressly not attempt to be all inclusive. The second part is a questionnaire ensuring patient comprehension. Thirdly, the family physician might use an "Informed Consent Checklist" to help make sure he or she transmits information, an excellent documentation device. In one practice⁵⁸ the physician has three general areas to check: informed consent, patient's anxiety leading to use of "therapeutic privilege," and the patient chooses to waive the right to be informed. The section for informed consent includes boxes to check for the side effects discussed (minor common and serious rarer side effects), risk/benefit ratio, alternative treatments, estimated duration of treatment, need for cooperation and openness, benefits, precautions, patient's understanding, questions asked, patient's verbal agreement. These areas are not itemizations of all the risks for a given treatment, but allow the physician to make sure each area is touched upon in every case. Thus, later testimony might well be needed to state what precise risks were discussed, but the areas of patient understanding can be more carefully attended to than would be otherwise.

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