THE PARAMETERS OF INFORMED CONSENT

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ABSTRACT

Purpose: To describe the components of a proper informed consent; which risks must be disclosed and which need not; additional safeguards for incapacitated persons, minors, and research subjects; and where the law will imply consent that is not otherwise obtained.

Methods: Summarization of current law obtained from legal treatises, reports of recent cases, and personal experience as a reviewer and expert.

Results: Lack of informed consent can reinforce a claim of medical malpractice or serve as an alternative point of attack when the case is otherwise weak. Special requirements must be met when patients are the subjects of clinical research.

Conclusion: Demonstration of a well-conducted process, not merely of a paper, not only protects the physician from exposure to liability, but increases the patient's autonomy in decisions concerning health and encourages compliance with treatment.

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INTRODUCTION

This presentation reviews informed consent as it applies not only to the practice of ophthalmology but to the practice of all areas of medicine. In most instances the informed consent process flows naturally from the "partnership" between physician and patient; however, when this does not occur, serious legal and ethical consequences may result.

METHODS

This discussion is based on review of legal decisions and commentary and on my personal experience as a reviewer and expert in medical malpractice cases. I have utilized case reports and several informative writings that have appeared in the *New York Law Journal* and *The Journal of Legal Medicine*, as well as selections from a vast amount of material available on the LexisNexis database. This report is not intended to be specific advice on any private legal matter.

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RESULTS

Lack of informed consent is a claim that can win for the plaintiff even when the malpractice claim is weak. Better understanding of the informed consent process is likely to protect and advance the interests of both patient and doctor.

DISCUSSION

Battery

Informed consent begins with consideration of the tort of battery, one of the oldest forms of legally disfavored conduct. It consists of unpermitted, unprivileged, intentional contact with another's person. The contact need not result in bodily harm; the intended contact itself is the harm.

Society's original interest in consent was as a peacekeeping device.[1] Battery provoked revenge, which threatened the public peace. The offensive conduct became acceptable if its recipient consented and thereby waived revenge.

In the medical context, it is legally well established that everyone of sufficient age and soundness of mind has the right to decide what is to be done to his or her body, even when survival is implicated.[2] Treatment with no consent at all, actual or implied,[3] treatment substantially different from that to which the patient consented,[4,5] or unauthorized substitution of one treater for another[6] come within the definition of battery, especially when

involving invasive procedures. That an unpermitted medical treatment may be lifesaving or curative, except in situations where consent would be implied (discussed below), does not excuse battery. The following actual case[7] is illustrative:

> A physician determined that a patient required surgery on the right ear. The patient gave informed consent to the procedure. With the patient under general anesthesia, the surgeon operated on the left ear, which at the subsequent trial he said required the same procedure. There were complications and resulting damage from the surgery. The patient took an easier route than proving negligence by obtaining a verdict of battery, despite the surgeon's best intentions.

In this case, consent to treatment of the right ear did not imply consent for the other ear despite the similarity in indications. Had life or hearing been immediately threatened, the result might have been otherwise. A point of practical significance is that as an intentional tort, battery is not within the scope of the physician's malpractice liability coverage, and because it is considered a wrong against society at large requiring a strong deterrent, there is the possibility of punitive damages.

Informed Consent

The patient's consent distinguishes permitted from unpermitted treatment. Whereas this effectively precludes a claim of battery under present-day conventions, it otherwise is insufficient to eliminate all legal risk. The right of choice under the concepts of autonomy and personal dignity is now legally recognized to require more.[8] Some authors have advocated deeming lack of informed consent as an invasion of these rights, actionable as battery.[9-11]

A claim of lack of informed consent usually accompanies an allegation of medical malpractice for wrongful diagnosis or treatment. It differs importantly from malpractice in not requiring that the treatment be a departure from the standard of care. The elements of the claim are (1) the physician did not present the risks and benefits of the proposed treatment and of alternative treatments; (2) with full information, the patient would have declined the treatment; and (3) the treatment, *even though appropriate and carried out skillfully*, was a substantial factor causing the patient's injuries.[12,13]

That the physician acted entirely in good faith is not a defense. Expert testimony usually is required to establish what the patient should have been told, but jurisdictions are divided on whether expert opinion is required as to what the patient would have decided if properly informed.[14]

Although the legal analyses for malpractice and informed consent are similar,[15] these are distinctly separate causes of action. Malpractice addresses the patient's interest in competent care, whereas lack of informed consent implicates self-determination.[10] Success on the latter issue will enhance a favorable verdict for the plaintiff and is a convenient fallback position when the malpractice case is weak. Some attorneys feel that juries are more comfortable with lack of informed consent as a basis for an award, because it avoids a malpractice branding of the defendant physician while addressing a sentiment that the patient should be compensated.

In contrast to the Canadian position that consent requires only broad discussion,[16] at least some US courts have held that consent is a nullity unless it is obtained completely consistent with the informed consent process, that is, there is either informed consent or no consent at all.[17-19] That this is not the prevailing sentiment is largely due to public policy considerations, so as not to be harsh enough on physicians to possibly affect delivery of medical care.

Disclosure

Almost all courts scrutinize the adequacy of informed consent under principles of negligence. Courts apply either of two standards for adequate disclosure, depending on the jurisdiction. Whether either one is breached is a question for the jury. One refers to what a reasonable physician would consider important to the patient's decision (the "reasonable practitioner" standard).[20] The other is whether the physician has disclosed what a reasonable person in the patient's position would want to know in order to make a considered decision (the "prudent patient" standard).[17,21] The latter was first adopted because of the perceived "conspiracy of silence" among the medical profession, making it unlikely that a plaintiff could obtain the requisite expert testimony to establish the defendant doctor's omissions.

Ideally, these standards should coincide, but in practice they are differing legal concepts, applied on a state-by-state basis. The reasonable practitioner standard, or "doctor knows best," tends to ignore the concept of patient autonomy to decide what is acceptable regardless of the type and likelihood of risks involved. Some English courts have held that this does not include the right to disclosure of any alternative treatment considered by the patient's own doctor to be contraindicated,[22,23] a throwback to Hippocrates and Plato, who believed that comprehension of medical matters was irredeemably beyond people's capacity. The law has progressed from this type of paternalism, although it survived well into the 20th century, but today this remains as the standard in about half of the US states, in part as a response to the malpractice insurance

crisis of the 1970s.[19]

The reasonable patient standard emphasizes the patient's right of choice. However, it has been criticized as requiring estimation of what factors might control in the mind of a hypothetical "reasonable patient" and as not focusing on the particular individual whose need for information may be reasonable only to himself or herself.[8,17] Again, an actual case[24] is instructive:

> A young woman agreed to a recommendation of surgery for her injured knee. In preparation for the procedure, the surgeon referred her for an arthrogram (arthroscopy was not yet in vogue) to a radiologist who obtained informed consent and included among the disclosed risks the possibility of an adverse inflammatory reaction to the injected contrast medium. This occurred and was incorrectly diagnosed as a joint infection by a different orthopedic surgeon. Continuous infusion of antibiotics into the patient's knee for the supposed joint infection led to that very outcome.
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> At trial, the radiologist could not produce the patient's signed consent for the arthrogram, but his sworn testimony as to his invariable custom and practice of holding a thorough informed consent conversation persuaded the jury that he had indeed carried out this process. The first orthopedic surgeon, who was not responsible for performance of the arthrogram nor for holding the informed consent dialogue for this procedure with the patient, and whose own diagnosis and proposed treatment were entirely within the standard of care, was found by the jury on the basis of the patient's testimony to have omitted informing her that intensive physical therapy without surgery or the need for an arthrogram was a treatment option.

There are important lessons in this case. First, the radiologist could have been defended much more easily had his consent form been available to support his testimony. He won because he could convince the jury of a thorough conversation outlining the risks, benefits, and in this instance the limited alternatives to achieve visualization of the interior of the joint. Second, each participant in a treatment must describe his or her own aspect of it, but not that of any other participant.[12,24] Discussing the pros and cons of the proposed surgery was not part of the radiologist's obligation. Likewise, the orthopedic surgeon was not required to make disclosure about the arthrogram. The jury found him liable for not presenting an alternative to the operation, which the patient testified she would have elected.

Must all risks be disclosed? The law requires disclosure only of *material*, not trivial, risks that are reasonably foreseeable.[17,19] "One in a million" occurrences, risks obvious even to a layperson, and those that clearly would not result in refusal of treatment had they been disclosed constitute other exceptions. As in malpractice, these situations turn on their particular fact contexts.

There also is an allowance for risks whose disclosure, in the physician's best judgment, would be emotionally harmful. Since assertion of this defense is clearly self-serving and not accepted by all courts, it is best avoided.

Some courts[25,26] and commentators[27] have considered the degree of the physician's experience with a treatment to be a material risk factor requiring disclosure with or without a query. Other courts[18] have not adopted this approach, stating that information regarding the skill and experience of a doctor is not relevant to understanding the risks of the treatment itself. Other potential concerns that have led to similar debate involve personal medical[28] and financial interest[29] factors that could affect the treating physician's skill and judgment.[8]

Another familiar dilemma is what a doctor should tell a patient about the risks of general anesthesia. Although undeniably a profound consequence, the risk of anesthetic death to a patient whose general health is reasonably good takes the inquiry into the range of unforseeability, yet clearly a reasonable patient would want to be aware of it. But what if disclosure would result in refusal of what, under the particular circumstances, clearly would be the best treatment alternative? There is no definite answer to this difficult problem.

A proper informed consent dialogue requires that the patient receive the information in ordinary terms and in his or her customary language, translated if necessary. There must be the opportunity to decide free of duress, although this does not prevent the physician from offering a recommendation based on expertise and judgment. Disclosure should always include the possibility of no treatment at all and the anticipated consequences of that course. Any undisclosed treatment alternatives, or withholding the option to do nothing, can be construed as an imposition of the physician's choices upon the patient's power to decide.[8]

Documentation

The informed consent process has been criticized as concentrating more on avoidance of physician liability than on truly educating patients so that they might make self-determined medical decisions.[30] This observation cites the consent form for support of this proposition, as it shapes what is intended as a process of dialogue and discussion into a discrete paper-signing event.

Instead, these critics advocate an autonomy-enhancing model in which the patient, by way of continuous

acquisition of information from the physician, remains master of the consent process. This approach emphasizes "informed" over mere "consent" and is facilitated by providing the patient a full opportunity to raise questions. As a beneficial side product, studies have shown that this model of informed consent, by giving the patient a greater sense of control, encourages compliance with treatment.[31] To date, this view has not prevailed either in customary medical encounters or in the courts.

Minors and Incapacitated Persons

For both adults and minors requiring emergency life- or function-preserving treatment, the law implies full consent except where it is clear from prior information that this has affirmatively been refused. This exception applies also to the extension of a planned surgical procedure on an anesthetized patient because of circumstances becoming evident only during the course of the operation.

In our practices, sometimes we are confronted with an unaccompanied minor presenting for routine examination. Even without invasive treatment, the examination represents "contact" for which the physician has no permission, especially for the use of cycloplegic drugs.

Parents or a legal guardian are responsible for health care decisions for an underage child. Many states allow adolescents to consent for purposes such as obtaining contraceptive devices, prenatal care, or screening and treatment for sexually transmitted diseases. Minors who are married, pregnant, parents, self-supporting, or a member of the military (so-called emancipated minors) generally are fully able to give consent in all health matters.

Unless the child fits into one of these categories, the best course in this situation would be to require written authority or consent by telephone. The latter presupposes a good faith belief that the appropriate person at the remote location has been contacted. In urgent but not emergency situations, a relative or adult sibling is deemed to have this authority without formal delegation.

Persons whose ability to understand and choose appropriately is questionable, unless already under judicially decreed guardianship, may require psychiatric consultation, as a New York court recently has held.[32]

Informed Consent for Research Subjects

Courts have evolved from the strong presumption that all nontraditional practices are outside the standard of care[33,34] to a recognition that investigation requires a different analysis.[35] Originally, the intent was to control quack remedies. Beginning in about 1935, the necessity for medical experimentation became more evident.

Initially, clinical research was largely unregulated and ethical matters such as consent and safety monitoring remained in the hands of the investigators. Special concerns arose in the aftermath of Nazi medical experiments during World War II, which resulted in the Nuremberg Code and the Declaration of Helsinki.[36] In the 1970s, certain research abuses led to Congressional action to protect human subjects,[37,38] leading to comprehensive regulations, known as the Common Rule, under which most therapeutic trials are now conducted,[39] including those involving drugs or devices regulated by the Food and Drug Administration.[40] The regulations meticulously spell out the informed consent requirements and provide that they be monitored by local institutional review boards.[38]

In addition, there is an in-between category of "innovative therapy," a single or limited number of unproven interventions, such as an off-label use of a drug, intended to solve an immediate clinical problem in an individual patient when the usual treatment options have not been effective or appropriate.[11,41] Penalization for the treatment of amblyopia, now well accepted, was at one time such an innovation. Without prior formal study of safety and efficacy, these nonvalidated practices also expose patients to greater risk, and it has been urged but not required that their use should be within the framework of a research protocol.

The difference between the conventional treatment and research settings is not only the comparative uncertainty of risks and benefits, but also the difference in objectives. To be approved by institutional review boards, the informed consent process must make the patient recognize that such studies are done to develop new knowledge that later may be valuable to a broader population of patients.[11,42] The purpose of the trial is not to make the individual subject well, although this may occur fortuitously.[11]

The investigator's first loyalty is to the protocol, not to the patient. Subjects may have to forego all treatment or an adjustment in dosage, or may experience unexpected and unpleasant side effects.[11] As some authors[42,43] have pointed out, this itself is a conflict of interest requiring meticulous disclosure. It is entirely possible that the subject will not be told of treatment alternatives outside the experimental protocol that could be elected by declining to participate. If a subject enrolls solely because of hoped-for benefits, any informed consent process has failed.

Recently, there has been a trend toward lawsuits for harm to research subjects,[44] including an action for enrolling premature infants into a high-oxygen study without parental knowledge and consent.[45] As the widely known DES litigation[3] illustrated, courts formerly analyzed informed consent mostly under the standard for conventional treatment, although now claiming to recognize that there is a special duty of care,[10,44,46,47] but the judi-

cial response has not always been consistent with the sentiment that loss of the right to personal dignity is a separate and unique wrong to which traditional malpractice and informed consent principles do not fully apply.[9-11,48]

The main informed consent safeguards are that the patient know that he or she is an experimental subject and possibly a control[49]; that the effects of the treatment are not entirely known and that withdrawal from the study is permissible[36]; that there is a Data and Safety Monitoring Board and that the study will be discontinued if, as occurred in the high-oxygen study,[45] the treatment convincingly shows an adverse effect; that there is a statement of the subject's rights and that they may not be waived[36]; and that there is a study privacy policy. Some authors[50] have stated that for informed consent to be complete, discussion of risks should include remotely suspected as well as known risks, because in this special context it is the patient who should determine which risks are material to the decision to participate.

Informed consent authority for minors and adolescents follows similar rules to those applicable to the usual clinical situation. Institutional review boards generally have specified that obtaining assent of the child in addition to that of the responsible guardian is an integral part of the process, but in the absence of specific regulatory guidelines, the threshold age for this requirement has varied.[51]

It has been suggested that the federal regulations, rather than the views of experts, should constitute the standard for disclosure. There is precedent for this for ophthalmology in cases involving intraocular lens implantation when this technique still was in the experimental stage.[52,53] Expert opinion on compliance with the standard remains appropriate, and compliance should provide a partial if not a complete defense.[10,54]

To summarize, informed consent should be thought of as a process, not as a paper. The document is helpful to memorialize what should have occurred before the patient's signature is obtained. The process should be appropriate whether the setting is one of conventional clinical practice or of an investigative study, and requires disclosure of information and its implications to a person with capacity who understands what is disclosed and voluntarily makes a decision. This is sound both legally and ethically.

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DISCUSSION

Dr Richard L. Abbott. In his paper, Dr Raab discusses important parameters of the informed consent process that are often neglected or overlooked by the busy clinician and can be used against the physician in a medical malpractice case. Some of these components include disclosure of risks and possible alternatives, the experience of the physician, risks from anesthesia, and off-label uses of a device or medication.

He emphasizes that malpractice and informed consent issues are distinct causes of action and that a claim of inadequate or improper informed consent is a convenient fallback position when the malpractice component of the claim is weak. In a recently published study looking at malpractice predictors and risk factors for ophthalmologists performing PRK and LASIK surgery, improper informed consent was found as the main cause for negligence in 30% of the claims and suits studied.[1]

The social goals of medical malpractice litigation are to deter unsafe practices, compensate patients injured through negligence, and exact corrective justice.[2] Many consumer groups view litigation as an indispensable form of protection against medical carelessness. Recently, it was estimated that one of six practicing physicians are faced with a malpractice claim each year.

For Ophthalmologists, the probability of incurring a claim or suit during a 35 year career is 95%. (Ghezzi T, unpublished data, 1998) Several factors have been linked to patients' decisions to file malpractice claims against their physician. Most commonly these have been dissatisfaction with treatment outcome and inadequate physician communication and interpersonal skills.[3] Unfortunately, busy schedules and time consuming administrative duties often make it difficult for ophthalmologists to develop the dialogue necessary to minimize unrealistic patient expectations. The ACGME has recognized the importance of interpersonal and communication skills by including these qualities as one of the six general competencies for assessment in the Maintenance of Certification process. Since informed consent is based on a shared decision between the physician and the patient, the ability of the physician to communicate effectively with the patient is crucial to the process.

Dr Raab raises many key points in his discussion of informed consent, emphasizing the importance of disclosure and in what detail a patient must be told regarding the nature of the risks, benefits, alternatives, and complications involved in the recommended treatment. In my experience, this issue often is debated regarding whether or not the patient needed to know all possible complications and what specifically needed to be documented in the medical record.

A second issue that is raised by Dr Raab in his paper discusses the disclosure of the physician's experience with a particular treatment and whether that should be offered to the patient as part of the informed consent process. This discussion with the patient has both ethical and legal implications and no clear-cut answer to this difficult dilemma emerges in the paper.

Finally, a review of the issues unique to the informed consent process for research subjects enrolled under IRB protocols and the use of off-label treatments leads the reader to consider several difficult and complex issues. Among these are: conflict of being an investigator and one's loyalty to the protocol (rather than the patient); inconsistent judicial response regarding special duty to care; failure of the informed consent process if a subject has enrolled in the study solely because of hoped for benefits.

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Dr Robert C. Drews. Informed consent, by definition, consists of education of the patient. I would suggest that the education process in any other setting always includes an examination or quiz to see if the patient understood the material that was being presented. It is disconcerting to find out how poorly patients understand all of the material you so diligently presented to them. A written copy of the quiz can go a long way toward satisfying the needs of an informed consent.

Dr Dennis M. Robertson. We published a report on informed consent about 25 years ago[1] in which patients were given a questionnaire after informed consent about retinal surgery. Patients remembered about half of what they were told even though we asked them questions relative to information in the informed consent discussion within 48 hours of the surgery. They also denied ever hearing about issues that we had clearly covered, and they confabulated. You may be interested to know that Mayo Clinic in Rochester has no written informed consent. The patients do not sign informed consent for surgery. It's different for IRB protocols involving research since the patients must sign an informed consent. But, for other surgical procedures and interventions, we merely write in our notes that the patient was informed about the process, about the disease, about the interventions, the risks and uncertainties, and the natural course. This is different at Mayo Clinic in Jacksonville, Florida, where, by state law, patients must sign an informed consent for surgical procedures.

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Dr Arthur Jampolsky. If one tells a patient that at worst you may die or may you lose the eye or go blind, and then fills in with some of the major things, does that add anything to coverage of things that might be omitted?

Dr David L. Guyton. Some of the angriest patients I see in my strabismus practice are those who see double after cataract surgery and occasionally after posterior segment retinal scleral buckle surgery as well. We now know that the incidence of anesthetic myotoxicity causing double vision after cataract surgery from retrobulbar or peribulbar anesthesia is about one in 200, and after retinal scleral buckle surgery, maybe as high as five to 10 percent, although that's hidden in the other causes of diplopia and tropias after scleral buckle surgery. Invariably, these patients state that they were not told about possible double vision after cataract surgery. Is this level of incidence something that really needs to be brought to the profession's attention? If it is not in such informed consent or informed consent documents, should it be, at that level of one in 200 cases?

Dr David R. Stager, SR. A refractive surgeon from Canada spoke at our group bimonthly meeting recently and he had a list of eight questions that he asks all his potential refractive surgery patients. He said that this gives him a profile of the patient who is destined to be unhappy. Is there a way of predicting patients for elective surgery who may be at a much higher risk of being unhappy, no matter what is done or what consent form is provided?

Dr Edward L. Raab. I enjoyed Dr Abbott's thoughtful discussion, as he is very knowledgeable in this subject. The evident interest in this topic, shown by the number and content of the other discussants' remarks, also is extremely satisfying.

To respond to Dr Drews, I do not think that the patient has to be given a set quiz, but certainly the informed consent process includes asking the patient to raise any questions he or she may have once the doctor's part of the dialogue is over.

Several discussants said that we give the patient informed consent. In fact, you take the patient's informed consent. What you give is the information; the consent is what comes back to you. Informed consent is a process that should be documented in your charts. In the research setting, it is mandated by your IRBs, which are responding to regulations that have been set forth by the federal government.

Dr Jampolsky asks whether, if you tell a patient the worst-case scenario, that embraces everything in between? My answer to that is "no," and I do not tell patients they can die under anesthesia unless in response to a direct question. The worst-case scenario is almost in the realm of the unforeseeable, and all the risks that are short of that are more foreseeable. Those are the ones that the law requires you to particularly inform about.

Dr Guyton wonders if a one-in-200 risk is something that should be revealed to the patient. There's no number, no bright line on something like that. For me, a one-in-200 risk is really not a high-level risk. But you will never find me, nor will I find you, in a jury box. Jurors are lay-

people and lawyers spin arguments. Although I don't think that's a very large risk, numerically, I probably would include it.

Dr Stager asks whether there is a profile of the liable-to-be-unsatisfied patient? I think we all have our gut feelings about this, but probably it is a question for a psychologist.

Thank you for the opportunity to contribute to our program.