informed consent

James E. Ludlam

American Hospital Association

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American Hospital Association
840 North Lake Shore Drive
Chicago, Illinois 60611

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foreword

The matter of an informed consent is of immeasurable importance to the patient and to the attending physician. It is also important to the hospital, but the hospital's interest will reflect its desire to assist members of its medical staff in meeting their obligations to the patient and in protecting the patient's welfare, as well as the instances in which the physician may be considered a hospital employee in legal contemplation.

The issue of informed consent has tended to become surrounded by some mystique and uncertainty, due in part to the variety of judicial and statutory developments that have taken place among the states. Among the purposes of this book, commissioned by the American Hospital Association, are to bring more light to the subject by focusing on the underlying principles and rationale of informed consent and to identify the somewhat disparate paths the doctrine has taken at the hands of different courts and state legislatures. To assist our readers in researching their own state's law, a list of authorities cited, including cases, statutes, law reviews, and other references, has been provided. The author has also documented the judicial development of required consents, provided an overview of relevant state statutes, and suggested a model statute when a legislative approach is thought to be appropriate.

Because informed consent is a matter regulated by state law, it lacks uniformity. For this reason in particular, the study should be regarded as one for reference and general information only and not to be used for legal guidance. While this publication will provide a useful reference for attorneys for both the practical and

legal considerations that relate to the doctrine, it is commended to all persons involved in the health care field, including particularly those who participate in developing legislative programs.

The author of the study is James E. Ludlam (B.A., Stanford University, 1936; J.D., Harvard Law School, 1939), an attorney who is both prominent and well versed in the law of the health care field. Although the AHA provided the author with considerable assistance and support, including staff research by Yvonne N. Bryant, former staff attorney in the Office of the General Counsel, the views are his own and do not necessarily reflect policies or positions of the American Hospital Association.

Richard L. Epstein
Vice-President
American Hospital Association

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chapter 1

introduction

Why a special publication on the subject of "informed consent"? This question can best be answered by responding that the issue is highly complex, involving issues of law, morality, and ethics and, further, that it is the cause of continuing controversy among the multiple parties of the health care team in their relation to one another. To oversimplify the concept, it can be said that informed consent is nothing more or less than good medicine. It may involve such highly publicized issues as the army private who is unknowingly administered LSD as part of a CIA experiment or the welfare mother being sterilized without her knowledge or consent. On the day-to-day level of activities, it may mean disclosing to a female patient the possible future risks of pregnancies where a tubal ligation has been performed.

One writer, in the October 1977 issue of *Trustee*, described the concept of informed consent as being the "patient's most important right."

The American Hospital Association, seeking to clarify the relationship between hospital, physician, and patient, published *A Patient's Bill of Rights* in 1972. The document, submitted to hospitals for their consideration, included the following declaration:

> 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, such infor-

> mation for informed consent, should include but not necessarily be limited to the specific procedure and/or treatment, the medically significant risks involved, and the probable duration of incapacitation. Where medically significant alternatives for care and treatment exist, or when the patient requests information concerning medical alternatives, the patient has the right to such information. The patient also has the right to know the name of the person responsible for the procedures and/or treatment.

This statement summarizes the information that, in the opinion of many courts, a physician must communicate to his patient in order for the patient's consent to treatment to be truly "informed." A simpler definition of informed consent was offered by Justice Blackmun in the case of *Planned Parenthood of Central Missouri v. Danforth.* The plaintiffs in that case objected to a statute that required women, prior to submitting to abortion, to certify in writing that their consent to the procedure is "informed" and freely given. Justice Blackmun stated, in a footnote:

> One might well wonder, offhand, just what informed consent of a patient is. The three Missouri federal judges who comprised the three-judge District Court, however, were not concerned, and we are content to accept, as the meaning, the giving of information to the patient as to just what would be done and as to its consequences. To ascribe more meaning than this might well confine the attending physician in an undesired and uncomfortable straitjacket in the practice of his profession. *Planned Parenthood of Central Missouri v. Danforth,* 428 U.S. 52, 67 (1976).

From the viewpoint of the physician, the rhetoric and litigation over the issue of informed consent has constituted not only potential threat of a malpractice claim but also a basic change in the role of the physician. The physician is disturbed by the uncertainty of the definition of physician responsibility and the inability to predict whether the courts will ultimately find that he has fulfilled his duty. The physician's problem is compounded by his inability to determine in advance whether he has properly documented his professional responsibility. Many physicians find intellectual difficulty with the concept that not only does the patient have the right to participate in and control the ultimate medical decision but the patient has the right to make the "wrong medical" decision. Although hospitals have less direct involvement than physicians, their vital concern with informed consent is very evident in the health care field. These concerns are discussed on pages 14-17.

The purpose of this publication, of necessity, is something less than an encyclopedic discourse on all of the nuances of the subject. It is hoped that it will give members of the health care team a basic definition and understanding of the importance of the doctrine as well as appropriate application in the everyday practice of health care. In addition, it provides an up-to-date analysis of both the court cases and statutes on the subject for the reader interested in the technical phases of the law. Also, there is a suggested model statute in chapter 5 and a review of one state's specific experiences in chapter 6.

One last warning to the reader. Despite its earlier origins, the concept of informed consent is an essentially new one in the law (the first case in recent times being in Kansas in 1960) and has not fully matured. What we say today will be modified and changed as the social pattern of action and reaction take place. For example, the statutes seeking to define or limit the application of the doctrine are reactions to the court cases that first declared certain moral and ethical principles relating to medical practice to be a basis for liability in law.

chapter 2

a contemporary overview

In 1972, the American Hospital Association Board of Trustees approved and released for consideration by its membership a statement entitled *A Patient's Bill of Rights*. This document was widely acclaimed by the media as being a statesmanlike approach to a much misunderstood role. AHA considered the principal purpose of *A Patient's Bill of Rights* as a method of informing the members of the public of their rights within the health care system and of prompting them to seek and utilize these rights. By setting forth these rights in a simple but complete document, the AHA affirmatively called attention of both the public and the health care providers to how far and how rapidly both the interrelationship between the patient and the health care provider had changed.

Included as one of the most important of the identified rights was that of an informed consent. The AHA statement on this issue declared:

> 2. The patient has the right to obtain from his physician complete current information concerning this diagnosis, treatment, and prognosis in terms the patient can be reasonably expected to understand. When it is not medically advisable to give such information to the patient, the information should be made available to an appropriate person in his behalf. He has the right to know by name the physician responsible for coordinating his care.

> 3. 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, such information for informed consent should include but not necessarily be limited to the specific procedure and/or treatment, the medically significant risks involved, and the probable duration of incapacitation. Where medically significant alternatives for care or treatment exist, or when the patient requests information concerning medical alternatives, the patient has the right to such information. The patient also has the right to know the name of the person responsible for the procedures and/or treatment.
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> 4. The patient has the right to refuse treatment to the extent permitted by law, and to be informed of the medical consequences of his action.

The issue of informed consent is most often raised in medical malpractice cases. If the patient has received a bad result and the issue of negligence is weak, the plaintiff's attorney will allege and seek to prove a lack of informed consent. Such an allegation will not only buttress a weak case on medical negligence but will also help ensure the plaintiff against a sustained demurrer or nonsuit. The most recent report by the All Industry Committee Special Malpractice Review: 1974 Closed Claim Study indicated that a lack of informed consent was alleged in 14 percent of malpractice cases brought. However, it is believed that the practice of pleading the lack of informed consent has materially increased since the 1974 study.

The concern for the lack of informed consent reflects a fundamental change in the relationship between the health care provider and the patient. Superficially, this change in relationship could be described as the age of consumerism in the health field, but to consider this as consumerism is to oversimplify both the complexities and the significance in the change that has occurred. Furthermore, one can observe that the change in relationship has not completed its cycle and that we are only in midstream. During the past 20 years of development of the concept, the emphasis has been the duty of the physician to his patient, on the one hand, and the newly defined (although long recognized) rights of the patient, on the other. It is anticipated that in the future the circle will be completed and emphasis will be on the obligation of the patient to the health care system. The earliest statements on *A Patient's Bill of Rights*[1] included a parallel statement of the patient's responsibility. With the present emphasis

on the recognition and codification of the patient's rights in his relationship to the health care system, his reciprocal responsibility for his own health care and his obligation to the health care system have been temporarily overlooked.[2] However, in the recent American Bar Association Commission on Medical Professional Liability report, these reciprocal duties are spelled out.[3] Since these duties have a potentially great impact on the increasing cost of health care, one can expect increasing emphasis on them.

How, then, does the newly expounded concept of informed consent that has developed in the past 20 years in the health field differ from the historic legal doctrine of consent? Historically, a medical consent was merely a granting of permission by a patient or the patient's legal representative to an assault or battery upon the patient. Even though it could be assumed that the fact that the patient was presented to the health care provider for care was, in itself, a consent with the potential of a simple touching or something more significant anticipated, this was not necessarily conclusive proof. The matter of proof of the consent was a potential question that could best be documented by a simple signed consent. As a result, the signing of a broad consent form with no explanation became routine practice in hospitals and doctors' offices. On occasion, the patient or the patient's representative may have signed the form along with a number of other forms routinely without question. The patient did not presume to question the forms. Sometimes the hospital admission clerk or the secretary in the doctor's office would have been medically unqualified to answer any pertinent question. From a legal point of view, the litigated questions related almost entirely to the competency of the signing individual, and these are primarily questions of contract law in the most basic sense.

The practice of medicine has become more complex with far more alternatives to the method of treatment. Furthermore, the potential dangers of various forms of available treatment have become far greater. These factors, coupled with the increased

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1. Report of the Secretary's Commission on Medical Malpractice, DHEW Publication No. (OS) 73-88, pp. 71-73.
2. AHA. *A Patient's Bill of Rights.* AHA: Chicago, 1972.
3. American Bar Association, 1977 Report of the Commission on Medical Professional Liability, p. 24.

expectations of patients for receiving a miracle cure, have created a new tension between the patient and the health care provider. A further complicating factor is that the patient is no longer dealing with his family physician with whom he has had a long relationship of mutual confidence and trust. In the hospital in particular, the patient faces a bewildering spectrum of specialists and consultants who are often, at best, a vague name and an overwhelming presence.

As a consumer of health services, the patient has the same rights as the consumer of other products to a full and fair disclosure of the product's inherent hazards. The anachronistic legal doctrine of "buyer beware" no longer applies. In addition, there has been increased emphasis on the fiduciary role of such professionals as lawyers, accountants, ministers, and the like, with the physician-patient relationship being described in similar terms. Both federal and state legislatures have also mandated additional burdens of disclosure upon the health care provider, for example, the federal swine flu legislation and various state statutes relating to sterilization and abortion. The requirements for disclosure of the hazards of smoking tobacco are all a part of this social trend. Much greater emphasis is being placed on the disclosure of hazards as distinguished from the actual prohibition of the product or procedure—the most dramatic recent example being the legalization of Laetrile by many state legislatures. In other words, not only does the patient-consumer have the right to know, but legislation may give him the right to exercise his own judgment and to defy all of the scientific and professional judgments to the contrary.

The Patient

All of the above factors and many more have led to the recognition that the patient has the right to participate in decisions affecting his physical and mental welfare, and if the patient is to exercise this right, then the patient must be informed. For this right to be effective, there must also be a correlative duty on the part of the provider to do the informing, and this results in the burden placed upon the health care providers.

Although the following list is not necessarily of a legal nature, the author would define the rights of the patient in this way:

1. The patient should know the nature of his problem and the progress of the diagnosis by the physician. Obviously, this is not

simple in actual practice, as the physician may be exploring a number of alternatives, some of which, though remote, would be extremely alarming to the patient. However, if the patient is to be fully cooperative, the patient must be informed as to major developments in the diagnosis.

2. The patient must be informed as to the alternative courses of treatment as the diagnosing proceeds. Such information must include both the risks and advantages of the alternatives. As a course of treatment is developed, decisions must be made as to when to abandon one course or to adopt another, so that there can be more than one critical decision during a span of time. Obviously, the physician will be expected to recommend a course so that an exposition of the positives as well as the negatives are of equal importance if the confidence of the patient is to be maintained.

3. A patient may properly waive his right to disclosure, but the physician should not overreach in his desire to achieve such a waiver. Many patients believe that they have made their choice by choosing the physician, and they place absolute faith in him to make the difficult decisions. A patient who is mentally coerced into a particular course of treatment will be the one most likely to react to an adverse result and challenge the validity of the consent.

4. The patient should be informed of the degree of risk, including consideration of both probability and severity. If there is a medically significant risk of death or serious injury, this must be exposed to the patient. Of concern to the physician is the fact that such exposition may lead the patient to reject a course of treatment that the physician sincerely believes to be in the best interest of the patient. However, we must keep in mind that the patient in some states may have the legal right to reject a course of treatment even though his physician is absolutely convinced that it is in the best interest of the patient.[4] The physician does have the right to withhold disclosure if, in his judgment, the patient is unable to handle the disclosure and if the disclosure would so affect the patient as to seriously affect his potential recovery. The physician must use reasonable judgment in making this decision.

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4. See discussion of patient's right to refuse treatment on p. 16.

5. State courts *should* recognize the right of the patient to reject treatment that will sustain life. Whether it is described as the "right to die with dignity" or the right to refuse heroic measures, the ultimate legal and social issue is the right, based upon adequate information, to determine what course of treatment is acceptable. In such a situation it is apparent that the patient must be adequately informed of the consequences of either accepting or rejecting the proposed course of treatment.

Although the above may be considered the big issues from the viewpoint of the patient, there are other issues between the patient and the health care system as a result of the need to inform the patient of matters relating to his case:

1. The patient may not be subjected to investigative or experimental procedures without the patient's consent—and such consent must be an informed one with all of the elements previously described.[5] No health care provider should engage in such procedures without having an established protocol that will ensure appropriate protective measures for the patient. These principles apply to the use of experimental drugs[6] and also to new or innovative procedures in surgery.

2. Participation by a patient in a teaching program is another area of potential conflict if the patient is not properly informed of the advantages and disadvantages of participating in such a program. No longer can we assume that the welfare patient has necessarily given up his right of privacy or waived his right to be treated with consideration simply because he is medically indigent. As more and more paying patients are, of necessity, utilized for teaching purposes, the need for formalized information procedures becomes increasingly important.

3. The patient has the right to be informed as to not only the identity of the practitioner who is responsible for his care but also the identity of those who may perform certain critical procedures.[7] He should not be subjected to surgery by nameless, unaccountable physicians. Although "ghost surgery" has long been declared to be strictly unethical by the American College of Surgeons and the American Medical Association, it has taken

5. See item 9 in AHA's *A Patient's Bill of Rights.*

6. FDA Regulations, 21 CFR, Part 310; HEW Regulations, 45 CFR, Part 46.

7. *A Patient's Bill of Rights.*

heroic efforts by the profession to eliminate this commercial practice. However, in the modern context of the teaching hospital, the role of the resident physician, who may assume full responsibility for the surgery of the patient, remains as a knotty problem of communication and disclosure. Fortunately, by the use of highly visible name tags, hospitals are making a major effort to identify personnel not only as to name but also as to professional qualification. The ubiquitous white jacket can be terribly confusing to an already intimidated patient. If the procedure involves a team approach, the patient should know the matter of the interrelation between the ancillary specialties, such as anesthesiology, radiology, pathology, and so forth.

4. Last, and perhaps one of the most controversial issues in relation to the patient's right to be informed, is the possible right of the patient to unlimited access to his medical record. The law on this issue is split. Some states recognize an almost unlimited right; others set up some barriers. Here is a classical conflict of the right of the patient to know and be informed and the need to maintain a continuous record of the diagnosis and treatment of the patient without fear of its being improperly used. For a record to be most useful from a professional point of view, it should include all objective observations including the pattern of diagnosis, which may require reference to and ultimate elimination of potentials, which, if known to the patient, would be highly disturbing. To permit the patient unlimited access to such material without some guidance can have a chilling effect on those required to maintain the record. The record of a mental health diagnosis can be particularly sensitive. Ultimately, the courts or the legislature will settle this conflict of social needs.[8]

The Physician

The right of the patient must be reflected in a duty by the physician. The term *physician* is emphasized rather than *health care provider* because in nearly all situations it is the physician who is primarily responsible for the informed consent. The attending physician is primarily responsible for the patient's care and as such is in the ultimate fiduciary capacity to the patient. All other participants of the health care team must be supportive of the attending physician's efforts.

8. *Gotkin v. Miller*, 514 F. 2d 125 (2d Cir. 1975).