

000001354

Statement

003089

25.06
E 84
1354

Ethical Dimensions of Informed Consent

Informed consent is an ethical concept that has become integral to contemporary medical ethics and medical practice. In recognition of the ethical importance of informed consent, the Committee on Ethics affirms that:

1. Informed consent for medical treatment and for participation in medical research is an ethical requirement (which legal doctrines and requirements can in part reflect).
2. Informed consent is an expression of respect for the patient as a person; it particularly respects a patient's moral right to bodily integrity, to self-determination regarding sexuality and reproductive capacities, and to the support of the patient's freedom within caring relationships.
3. Informed consent not only ensures the protection of the patient against unwanted medical treatment, but it also makes possible the active involvement of the patient in her or his medical planning and care.
4. Freedom is maximized in relationships marked by mutuality and equality; this offers both an ethical ideal and an ethical guideline for physician-patient relationships.
5. Communication is necessary if informed consent is to be realized, and physicians can help to find ways to facilitate communication not only in individual relations with patients but also in the structured context of medical care institutions.
6. Informed consent should be looked upon as a process, a process that includes ongoing shared information and developing choices as long as one is seeking medical assistance.
7. The ethical requirement of informed consent need not conflict with physicians' overall ethical obligation to a principle of beneficence; that is, every effort should be made to incorporate a commitment to informed consent within a commitment to provide medical benefit to patients and thus to respect them as whole and embodied persons.
8. There are limits to the ethical obligation of informed consent, but a clear justification should be given for any abridgement or suspension of the general obligation.
9. Because ethical requirements and legal requirements cannot be equated, physicians should also acquaint themselves with the legal requirements of informed consent.

The application of informed consent to contexts of obstetric and gynecologic practice invites ongoing clarification of the meaning of these nine statements. What follows is an effort to provide this.

HISTORICAL BACKGROUND

In 1980, the Committee on Ethics of the American College of Obstetricians and Gynecologists (ACOG) developed a statement on informed consent.* This statement reflected what is now generally recognized as a paradigm shift in

*1 - Am J Obstet Gynecol
2 - E 84*

*This statement, "Ethical Considerations Associated with Informed Consent," was subsequently approved and issued in 1980 as a Statement of Policy by the Executive Board of ACOG. In 1989, it was withdrawn for revision by the Committee on Ethics.

From the American College of Obstetricians and Gynecologists. Ethical Dimensions of Informed Consent (ACOG Committee Opinion 108). Washington, DC: ACOG, 1992.

© 1992 by the American College of Obstetricians and Gynecologists. Reprinted (with adaptation) with permission.

the ethical understanding of the physician-patient relationship. The 1970s had seen in the United States a marked change from a traditional almost singular focus on the benefit of the patient as the governing ethical principle of medical care to a new and dramatic emphasis on a requirement of informed consent. That is, a central and often sole concern for the medical well-being of the patient gave way to, or was at least modified to include, concern for the patient's autonomy in making medical decisions.

In the 1980s this national shift was both reinforced and challenged in medical ethics. Clinical experience as well as developments in ethical theory generated further questions about the practice of informed consent and the legal doctrine that promoted it. If in the 1970s informed consent was embraced as a corrective to paternalism, the 1980s exhibited a growing sense of need for shared decision-making as a corrective to the exaggerated individualism that patient autonomy had sometimes produced. At the same time, factors such as the proliferation of medical technologies, the bureaucratic and financial complexities of health care delivery systems, and the growing sophistication of the general public regarding medical limitations and possibilities continued to undergird an appreciation of the importance of patient autonomy and a demand for its safeguard in and through informed consent.

In the 1990s there are good reasons for considering once again the ethical significance and practical application of the requirement of informed consent. This is particularly true in the context of obstetric and gynecologic practice. Here medical options, public health problems, legal interventions, and political agendas have not only expanded but interconnected with one another in unprecedented ways. ACOG's concern for these matters is reflected in its more recent documents on informed consent and on particular ethical problems such as maternal-fetal conflict, sterilization, and surrogate motherhood.¹⁻⁹ While a general ethical doctrine of informed consent cannot by itself resolve problems like these, it is nonetheless necessary for understanding them.

Informed consent for medical treatment and for participation in medical research is both a legal and an ethical matter. In the short 20th-century history of informed consent, statutes and regulations as well as court decisions have played an important role in the identification and sanctioning of basic duties. Judicial decisions have sometimes provided insights regarding rights of self-determination and of privacy in the medical context. Government regulations have rendered operational some of the most general norms formulated in historic ethical codes.* Yet there is little recent development in the legal doctrine of informed consent, and the most serious current questions are ethical ones before they are ones of the law. As the President's Commission reported in 1982, "Although the informed consent doctrine has substantial foundations in law, it is essentially an ethical imperative."¹⁰ What above all bears reviewing, then, is the ethical dimension of the meaning, basis, and application of informed consent.

THE ETHICAL MEANING OF INFORMED CONSENT

The ethical concept of "informed consent" contains two major elements: *free consent* and *comprehension* (or understanding). Both of these elements together constitute an important part of a patient's "self-determination" (the taking hold of one's own life and action, determining its meaning and the possibility of what one undergoes as well as what one does).

Free consent is an intentional and voluntary act which authorizes someone else to act in certain ways. In the context of medicine, it is an act by which a person freely authorizes a medical intervention in her or his life, whether

*The Nuremberg Code in 1948 and the World Medical Association's Declaration of Helsinki in 1964 identified ethical restrictions for medical research on human subjects. For a history of the development of such codes and a general history of the ethical and legal concept of informed consent, see Ruth R. Faden and Tom L. Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986). A culminating summary of federal regulations in the United States can be found in the *Federal Register* (June 26, 1991).

in the form of treatment or participation in research. As "consent," it implies the opposite of being coerced or unwillingly invaded by forces beyond oneself. As "free," consent implies a choice between alternatives. It includes the possibility of choosing otherwise—as the result of deliberation and/or of identification with different values and preferences. Free consent, in other words, implies the possibility of choosing this or that option or the refusal of any proposed option.

Comprehension (as an ethical element in informed consent) includes awareness and some understanding of information about one's situation and possibilities. Comprehension in this sense is necessary in order for there to be freedom in consenting. Free consent, of course, admits of degrees, and its presence is not always verifiable in concrete instances; but if it is to be operative at all in the course of medical treatment, it presupposes some level of understanding of available options.

Many people who are thoughtful about these matters have different beliefs about the actual achievement of informed consent and about human freedom. Whether and what freedom itself is has often been disputed. Despite continuing differences in understanding philosophical perspectives, however, important agreement has grown in this society about the need for informed consent and about its basic ethical significance in the context of medical practice and research. It is still important to try to clarify, however, who and what informed consent serves, and how it may be protected and fostered. This clarification cannot be achieved without some continuing consideration of its basis and goals and the concrete contexts in which it must be realized.

THE ETHICAL BASIS AND PURPOSE OF INFORMED CONSENT

One of the important arguments for the ethical requirement of informed consent is an argument from *utility*, or from the *benefit* that can come to patients when they actively participate in decisions about their own medical care. That is, the involvement of patients in such decisions is good for their health—not only because it is a protection against treatment which patients might consider harmful, but because it contributes positively to their well-being. There are at least two presuppositions here: One is that patients know something experientially about their own medical condition that can be helpful and even necessary to the sound management of their medical care. The other is that, wherever it is possible, the active role of primary guardian of one's own health is more conducive to well-being than is a passive and submissive "sick role." The positive benefits of patient decision-making are obvious, for example, in the treatment of alcohol abuse. But the benefits of active participation in medical decisions are multifold for patients, whether they are trying to maintain their general health, or recover from illness, or conceive and deliver healthy babies, or live responsible sexual lives, or accept the limits of medical technology, or enhance whatever processes they are in that bring them to seek medical care.

Utility, however, is not the only reason for protecting and promoting patient decision-making. Indeed, the most commonly accepted foundation for informed consent is probably the principle of *respect for persons*. This principle expresses an ethical requirement to treat human persons as "ends in themselves" (that is, not to use them solely as means or instruments for someone else's purposes and goals). The logic of this requirement is based on the perception that all persons as persons have certain features or characteristics that constitute the source of an inherent dignity, a worthiness and claim to be affirmed in their own right. One of these features has come to be identified as *autonomy*—a person's capacity or at least potential for self-de-

termination (for self-governance and freedom of choice). To be autonomous in any degree is to have the capacity to set one's own agenda—in some important way to choose one's actions and even one's attitudes, to determine the meaning of the outcome of one's life. Given this capacity in persons, it is ordinarily an ethically unacceptable violation of who and what persons are to coerce their actions or to refuse their participation in important decisions that affect their lives.

One of the important developments in ethical theory in recent years is the widespread recognition that autonomy is not the only characteristic of human persons that is a basis for the requirement of respect. Human persons, it is noted, are essentially social beings, *relational* in the structure of their personalities, their needs, and their possibilities. Given this "relationality," then, the goal of human life and the content of human well-being cannot be adequately understood only in terms of self-determination—especially if self-determination is understood individualistically and if it results in human relationships that are primarily adversarial. A sole or even central emphasis on patient autonomy in the informed consent process in the medical context risks replacing paternalism with a distanced and impersonal relationship of strangers negotiating rights and duties. If persons are to be respected and their well-being promoted, informed consent must be seen as serving a fuller notion of relationship.

Patients come to medical decisions with a history of relationships, personal and social, familial and institutional. Decisions are made in the context of these relationships, shared or not shared, as the situation allows. Above all, these decisions are made in a relationship between patient and physician (or often between patient and multiple professional caregivers).

The focus, then, for understanding both the basis and the content of informed consent must shift to include the many facets of the physician-patient relationship. Informed consent, from this point of view, is not an end, but a means. It is a means not only to the responsible participation by patients in their own medical care; it is also a means to a new form of relationship between physician (or any medical caregiver) and patient. From this perspective it is possible to see the contradictions inherent in an approach to informed consent that would, for example:

1. Lead a physician (or anyone else) to say of a patient, "I gave her informed consent."
2. Assume that informed consent was achieved simply by the signing of a document.
3. Consider informed consent primarily as a safeguard for physicians against medical liability.

It is also possible to see, from this perspective, that informed consent is not meant to undergird a patient's unlimited demand for treatment, arbitrary noncompliance with agreed upon treatment, or whimsical withdrawal from an agreed upon research protocol.

Freedom is maximized in relationships of trust; understanding is enhanced in the nuanced frameworks of conversation. Self-determination need not be either combative or submissive, but situated in relationships of mutuality of respect and, insofar as possible, equality of personal power. These kinds of professional relationships represent the preferred context for informed consent.

OBSTETRICS AND GYNECOLOGY: SPECIAL ETHICAL CONCERNS FOR INFORMED CONSENT

The practice of obstetrics and gynecology has always faced special ethical questions in the implementation of informed consent. How, for example, can

the autonomy of patients best be respected when serious decisions must be made in the challenging situations of labor and delivery? What kinds of guidelines can physicians find for respecting the autonomy of adolescents, when society acknowledges this autonomy by and large only in the limited spheres of sexuality and reproduction? Do "recommendations" compromise patient autonomy in the context of genetic counseling? How much information should be given to patients about controversies surrounding specific treatments? How are beneficence requirements (regarding the well-being of the patient) to be balanced with rights of patient choice, especially in a field of medical practice where so many key decisions are irreversible? These and many other questions continue to be important for fulfilling the ethical requirement of informed consent.

Developments in the ethical doctrine of informed consent (regarding, for example, the significance that relationships have for decision-making) have helped to focus some of the concerns that are particular to the practice of obstetrics and gynecology. Where *women's* health care needs are addressed, and especially where these needs are related to women's sexuality and reproductive capacities, the issues of patient autonomy and relationality take on special significance. In other words, the gender of patients makes a difference where ethical questions of informed consent are concerned, because gender in our society has been a relevant factor in interpreting the meaning of autonomy and relationality. This is not to say that in some essential sense autonomy or relationality (or informed consent and relationships) ought to be different for women and men; indeed, quite the opposite. Rather, this alerts us to the possible inconsistencies in the application of the ethical requirement of informed consent.

While issues of gender are to be found in every area of medical practice and research,* they are particularly important in the area of obstetrics and gynecology. Of special relevance here, for example, are the insights now being articulated by women out of their experience—that is, their experience specifically in the medical setting, but also more generally in relation to their own bodies, in various patterns of relation with other persons, and in the larger societal and institutional contexts in which they live. These insights offer both a help and an ongoing challenge to the professional self-understanding and practice of obstetricians and gynecologists (whether they themselves are women or men).

Obstetrics and gynecology has in a special way seen new dimensions of informed consent emerge, and here new models for the active participation of health care recipients have been created. Some of these developments are the result of effective arguments that pregnancy and childbirth are not diseases, though they bring women importantly into relation with medical professionals. Even when women's medical needs are more precisely needs for diagnosis and treatment, their concerns to hold together the values of both autonomy and relationality have been influential in shaping not only ethical theory but also medical practice. Women themselves have questioned, for example, whether autonomy can really be protected if it is addressed in a vacuum, apart from an individual's concrete roles and relationships. But women as well as men have also recognized the ongoing importance of respect for autonomy as a requirement of moral justice in every relationship. Many women therefore continue to articulate fundamental concerns for bodily integrity and self-determination. At the same time they call for attention to the complexity of the relationships that are involved when sexuality and parenting are at issue in medical care.

The difficulties that beset the full achievement of informed consent in the practice of obstetrics and gynecology are not limited to individual and interpersonal factors. Both providers and recipients of medical care within

*See, for example, a recent study of court decisions on refusal of treatment regarding dying patients (Miles SH, August A. Courts, gender, and the "right to die." *Law Med Health Care* 1990;18(1-2[Spring-Summer]): 85-95). The conclusion of this study is that court decisions for women patients differ from court decisions for men; that is, in general, men's previously stated wishes about "extraordinary" or "heroic" measures of treatment are taken more seriously than are women's.

this specialty have recognized the influence of such broad social problems as the historical imbalance of power in gender relations; the constraints on individual choice posed by complex medical technology; and the intersection of gender bias with race and class bias in the attitudes and actions of individuals and institutions. None of these problems makes the achievement of informed consent impossible. But, they alert us to the need to identify the conditions and limits, as well as the central requirements, of the ethical application of this doctrine.

ETHICAL APPLICATIONS OF INFORMED CONSENT

Insofar as comprehension and free consent are the basic ethical elements in informed consent, its efficacy and adequacy will depend on the fullness of their realization in patients' decisions. There are ways of assessing this and strategies for achieving it, even though—like every event of human freedom—*informed consent* involves a process that is not subject to precise measurement.

It is difficult to specify what consent consists in and requires, for it is difficult to describe a free decision in the abstract. Two things can be said about it in the context of informed consent to a medical intervention, however, elaborating on the conceptual elements we have already identified. The first is to describe what consent is *not*, what it is freedom *from*. Informed consent includes freedom from external coercion, manipulation, or infringement of bodily integrity. It is freedom from being acted upon by others when they have not taken account of and respected one's own preference and choice. This kind of freedom for a patient is not incompatible with a physician's giving *reasons* that favor one option over another. Medical recommendations, when they are not coercive or deceptive, do not violate the requirements of informed consent. For example, to try to convince a patient to take medication that will improve her health is not to take away her freedom (assuming that the methods of convincing are ones that respect and address, not overwhelm, her freedom). Or in another example, an attempt to persuade a woman who has tested positive for the human immunodeficiency virus that she should communicate the results of her testing to medical personnel who will be treating her infant is not in itself coercive; it need not violate her freedom.

The second thing that can be said about informed consent to a medical intervention is that while it may be an authorization of someone else's action toward one's self, it is—more profoundly—an active participation in decisions about the management of one's medical care. It is therefore (or can be) not only a "permitting" but a "doing." It can include decisions to make every effort toward a cure of a disease; or when cure is no longer a reasonable goal, to maintain functional equilibrium; or, finally, to receive medical care primarily in the form only of comfort. The variety of choices that are possible to a patient ranges, for example, from surgery to medical therapy, from diagnostic tests to hormone replacement, and from one form of contraception to another. For women in the context of obstetrics and gynecology, the choices are often ones of positive determination of this kind of assisted reproduction or that, this kind of preventive medicine or that—choices that are best described as determinations of their own actions rather than the "receiving" of care as a "patient."

Consent in this sense requires not only external freedom but the internal freedom which is a capacity for self-determination. Internal freedom includes not only freedom from inner compulsion and fear, but (as we have already observed) freedom from ignorance. Hence, consent is specified as "informed," and it depends on the further specification of what "comprehension" means.

Because comprehension requires information, it implies the disclosure of information and a sharing of interpretations of its meaning by a medical professional. The *accuracy* of disclosure, insofar as it is possible, is governed by the ethical requirement of truth-telling.¹¹ The *adequacy* of disclosure has been judged by various criteria, including:

1. The common practice of the profession.
2. The reasonable needs and expectations of the ordinary person who might be making a particular decision.
3. The unique needs of an individual patient faced with a given choice.*

Although these criteria have been generated in the rulings of courts, the courts themselves have not provided a unified voice as to which of these criteria should be determinative. Trends in judicial decisions in most states were for a time primarily in the direction of the "professional practice" criterion, requiring only the consistency of one physician's disclosure with the practice of disclosure by other physicians. Now the trend in many states is more clearly toward the "reasonable person" criterion, holding the medical profession to the standard of what is judged to be material to an ordinary person's decision in the given medical situation. The criterion of the subjective needs of the patient in question has been generally too difficult to implement in the legal arena, though the force of its ethical appeal is significant.

Health care providers should engage in some ethical discernment of their own as to which criteria are most faithful to the needs and rightful claims of patients for disclosure. All three criteria offer reminders of ethical accountability and guidelines for practice. All three can help to illuminate what needs to be shared in the usually significant categories for disclosure: diagnosis and description of the patient's medical condition; description of the proposed treatment, its nature and purpose; risks and possible complications associated with the treatment; alternative treatments or the relative merits of no treatment at all; and the probability of success of the treatment.

Listing categories of disclosure does not by itself fill out all the elements that are important to adequacy of disclosure. For example, the obligation to provide adequate information to a patient implies an obligation for physicians to be current in their own knowledge, for example, about treatments, and disease processes. And when physicians make informed consent possible for patients by giving them the knowledge they need for choice, it should be clear to patients that their continued medical care by a given physician is not contingent on their making the choice that the physician prefers (assuming the limited justifiable exceptions to this that we will note below).

Those who are most concerned with problems of informed consent insist that central to its achievement is communication—communication between physician and patient, but also communication among the many medical professionals who are involved in the care of the patient, and communication (where this is possible and appropriate) with the family of the patient. The role of documentation in a formal process of informed consent can be a help to necessary communication (depending on the methods and manner of its implementation). Yet the completion of consent forms, however legally significant, cannot substitute for the communication of disclosure, the conversation that leads to free refusal or consent.²

To note the importance of communication for the implementation of an ethical doctrine of informed consent is, then, to underline the fact that informed consent involves a process. There is a process of communication that leads to initial consent (or refusal to consent) and that can make possible appropriate ongoing decision-making.

There are, of course, practical difficulties with ensuring the kind of communication necessary to informed consent. Limitations of time in a

*For an overview of legal standards for disclosure, and of ethical questions that go beyond legal standards, see Ruth R. Faden and Tom L. Beauchamp, *A History and Theory of Informed Consent* (New York: Oxford University Press, 1986:30-34, 306-316).

clinical context, patterns of authority uncritically maintained, underdeveloped professional communication skills, "language barriers" between technical discourse and ordinarily comprehensible expression, situations of stress on all sides—all of these frequently yield less than ideal circumstances for communication. Yet the ethical requirement of informed consent, no less than a requirement for good medical care, extends to a requirement for reasonable communication. The conditions for communication may be enhanced by creating institutional policies and structures that make it more possible and effective.

It is obvious that while disclosure and consent are basic ethical requirements and not only ideals, they admit of degrees. There will always be varying levels of understanding, varying degrees of internal freedom. The very matters of disclosure are of a kind that are often characterized by disagreement among professionals, uncertainty and fallibility in everyone's judgments, the results not only of scientific analysis but of medical insights and art. And the capacities of patients for comprehension and consent are more or less acute, of greater or lesser power, focused in weak or strong personal integration, compromised or not by pain, medication, or disease. Some limitations mitigate the obligation of informed consent, and some render it impossible. But any compromise or relaxation of the full ethical obligation of informed consent requires specific ethical justification.

THE LIMITS OF INFORMED CONSENT

Because informed consent admits of degrees of implementation, there are, then, limits to its achievement. These are not only the limits of fallible knowledge or imperfect communication. They are limitations in the capacity of patients for comprehension and for choice. Assessment of patient capacity is itself a complex matter, subject to mistakes and to bias. Hence, a great deal of attention has been given to criteria for determining individual capacity (and the legally defined characteristic of "competence") and for just procedures for its evaluation.¹² When persons are entirely incapacitated for informed consent, the principle of respect for persons requires that they be protected. Much attention has also been given to the ways and the means of this protection. In general, decisions must be made in these situations for the patient—either by attempts to give a "substituted judgment" (a decision based on what the patient would have wanted, assuming some knowledge of what the patient's wishes would be) or by a decision made according to the "best interests" of the patient. The relative merits of these two options depend on the concrete situation of the patient and those who know and care for her.

The judgment that informed consent is impossible in some circumstances indicates a kind of limit that is different from a minimized, or partial, actualization of consent. One way to acknowledge this is to say that there are limits to the obligation to obtain informed consent at all. Another way is to identify alternative means (for example, "substituted judgment") by which the values and goals of informed consent can be preserved. Both of these ways are perhaps served by saying simply that there are exceptions to the strict rule of informed consent. These exceptions are of several kinds.

First, *impossibility* of any achievement of informed consent suspends the ethical obligation. This is exemplified in emergency situations where consent is unattainable and in other situations where a patient is not at all competent or capable of giving consent. In the practice of obstetrics and gynecology, as in any other special practice, there are situations where decisions can be based

only on what is judged to be in the "best interest" of the patient—a judgment made, if possible, by family members (or a legal guardian) and medical professionals together. Yet often when a patient is not able to decide for herself (perhaps, for example, because of the amount of medication needed to control pain) a "substitute judgment" or a judgment on the basis of *prior* informed consent can be made with confidence if care has been taken beforehand to learn the patient's wishes. This signals the importance of early communication so that what a patient would choose in a developing situation is known—so that, indeed, it remains possible to respect the self-determination that informed consent represents.

A second way in which the rule of informed consent may be suspended is by being *overridden* by another obligation. There are a number of other ethical obligations that can in certain circumstances override or set limits to the extent of the requirement of informed consent. For example, strong claims for the *public good* (specifically, public health) may set limits to what a patient can choose or refuse. That is, the rights of others not to be harmed may sometimes take priority over an individual's right to refuse a medical procedure (as is the case of exceptional forms of mandatory medical testing and reporting). On the other hand, scarcity of personnel and equipment may in some circumstances mean that individual patients cannot have certain medical procedures "just for the choosing." Also, what is known as *therapeutic privilege* can override an obligation to disclose information and hence to obtain informed consent. "Therapeutic privilege" is the limited privilege of a physician to withhold information from a patient in the belief that this information about the patient's medical condition and options will seriously harm the patient. Concern for the patient's well-being (the obligation of beneficence) thus comes into conflict with respect for the patient's autonomy. This is a difficult notion to apply, however, and great caution must be taken in any appeal made to it. It should not, for example, be used as a justification for ignoring the needs and rights of adolescents to participate in decisions about their sexuality and their reproductive capacities. It is reasonable to argue that therapeutic privilege is almost never a basis for completely overriding the obligation of informed consent, and that when it is, it may characterize a temporary situation, one that will later allow the kind of communication conducive to the freedom of the patient.

Third, and finally* there are limits intrinsic to the *patient-physician relationship* that keep the requirement of informed consent from ever being absolute: Physicians are moral agents or decision-makers, too, and as such retain areas of free choice—as in the freedom not to provide medical care that they deem medically or ethically irresponsible (a freedom that is sometimes called a right to "conscientious objection"). Interpretations of medical need and usefulness may lead a physician, for example, to refuse to perform surgery or prescribe medication (though the physician should provide the patient with information about her medical options). In the mutuality of the patient-physician relationship, each one is to be respected as a person and supported in her or his autonomous decisions insofar as those decisions are not, in particular circumstances, overridden by other ethical obligations. The existing imbalance of power in this relationship, however, is a reminder to physicians of their greater obligation to ensure and facilitate the informed consent of each patient. That is, differences in professional knowledge can and should be bridged precisely through efforts at communication of information. Only in this way can decisions that are truly mutual be achieved.

Acknowledging the limits of the ethical requirement of informed consent, then, clarifies but does not weaken the requirement as such. In recognition of this, the ACOG Committee on Ethics affirms the nine statements with which this document began.

*Sometimes another exception to the rule of informed consent is thought to occur in the rare situation when a patient effectively *waives* her right to give it. This can take the form of refusing information necessary for an informed decision, or simply refusing altogether to make any decision. However, there are two reasons for not considering this an exception with the same status as the others listed here:

1. A waiver in such instances seems to be itself an exercise of choice, and its acceptance can be part of respect for the patient's autonomy.
2. Implicit in the ethical concept of informed consent is the goal of maximizing a patient's freedoms, which means that "waivers" should not be accepted complacently without some concern for the causes of the patient's desire not to participate in the management of her care.

In any case, it should be noted that in states where informed consent forms are required, it may be necessary to meet this requirement in some legally acceptable way.

REFERENCES

1. American College of Obstetricians and Gynecologists, Department of Professional Liability. Informed consent. The assistant. Washington, DC: ACOG, 1988.
2. American College of Obstetricians and Gynecologists, Department of Professional Liability. Informed consent forms. The assistant. Washington, DC: ACOG, 1988.
3. American College of Obstetricians and Gynecologists. Ethical decision-making in obstetrics and gynecology. ACOG Technical Bulletin 136. Washington, DC: ACOG, 1989.
4. American College of Obstetricians and Gynecologists. Patient choice: maternal-fetal conflict. ACOG Committee Opinion 55. Washington, DC: ACOG, 1987.
5. American College of Obstetricians and Gynecologists. Ethical issues in pregnancy counseling. ACOG Committee Opinion 61. Washington, DC: ACOG, 1988.
6. American College of Obstetricians and Gynecologists. Sterilization of women who are mentally handicapped. ACOG Committee Opinion 63. Washington, DC: ACOG, 1988.
7. American College of Obstetricians and Gynecologists. Ethical considerations in sterilization. ACOG Committee Opinion 73. Washington, DC: ACOG, 1989.
8. American College of Obstetricians and Gynecologists. Human immunodeficiency virus infection: physicians' responsibilities. ACOG Committee Opinion 85. Washington, DC: ACOG, 1989.
9. American College of Obstetricians and Gynecologists. Ethical issues in surrogate motherhood. ACOG Committee Opinion 88. Washington, DC: ACOG, 1990.
10. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical Research. Making health care decisions: the ethical and legal implications of informed consent in the patient-practitioner relationship. Vol 1. (Stock no. 040-000-00459-9). Washington, DC: U.S. Government Printing Office, 1982:2.
11. American College of Obstetricians and Gynecologists. Deception. ACOG Committee Opinion 87. Washington, DC: ACOG, 1990.
12. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical Research. Making health care decisions: the ethical and legal implications of informed consent in the patient-practitioner relationship. Vol 1. (Stock no. 040-000-00459-9). Washington, DC: U.S. Government Printing Office, 1982: Chapters 8-9.

BIBLIOGRAPHY

- Beauchamp TL, Childress JF. Principles of biomedical ethics. 3rd ed. New York: Oxford University Press, 1989:Chapter 1.
- Faden RR, Beauchamp TL. A history and theory of informed consent. New York: Oxford University Press, 1986.
- Katz J. The silent world of doctor and patient. New York: The Free Press, 1984.
- Levine RJ. Ethics and regulation of clinical research. 2nd ed. Baltimore, Maryland, and Munich, Germany: Urban and Schwarzenberg, 1986.
- The President's Commission for the Study of Ethical Problems in Medicine and Biomedical Research. Making health care decisions: the ethical and legal implications of informed consent in the patient-practitioner relationship. Vol 1. (Stock no. 040-000-00459-9). Washington, DC: U.S. Government Printing Office, 1982.
- The President's Commission for the Study of Ethical Problems in Medicine and Biomedical Research. Making health care decisions: the ethical and legal implications of informed consent in the patient-practitioner relationship. Vol 2. (Stock no. 040-000-00468-8). Washington, DC: U.S. Government Printing Office, 1982.
- The President's Commission for the Study of Ethical Problems in Medicine and Biomedical Research. Making health care decisions: the ethical and legal implications of informed consent in the patient-practitioner relationship. Vol 3. (Stock no. 040-000-00469-6). Washington, DC: U.S. Government Printing Office, 1982.