Introduction

What is informed consent to health care, and why has it assumed such an important place in legal and ethical discussions? Is it merely a rhetorical construct, imposed halfheartedly upon medicine by the law? Or is it perhaps a token of larger changes in the relationship between patients and health care professionals, especially physicians? And why does the concept have such importance in the United States today—because of a particular cultural attachment to independence and autonomy? The growing importance of biomedicine in people’s lives? Skepticism over “expertise” in many spheres? Or perhaps some combination of these and other factors?

These were among the basic issues before the President’s Commission during its Congressionally mandated study of “the ethical and legal implications of the requirements for informed consent to... undergo medical procedures.” Rather than embroider the doctrine of informed consent within the confines of the case and statutory law that was its source, the Commission decided early in its study to examine the subject within the broader context of relations and communications between patients and health care professionals. It wished to see whether means could be found to promote a fuller understanding by patients and professionals of their common enterprise, so that patients can participate, on an informed basis and to

1 42 D.S.C. § 300v-1(a)(1)(A) (1981) also instructs the Commission to study the implications of “informed consent to participation in research projects.” The Commission treats issues of human research generally in its biennial reports, PROTECTING HUMAN SUBJECTS. Furthermore, although they developed initially along independent lines, see note 19, Chapter One infra, the legal rules for informed consent to treatment and to participation in research spring from common legal and philosophical ground, have had parallel courses of development, and are now basically congruent, so that a separate discussion is not required in this Report.
the extent they care to do so, in making decisions about their health care.

**Summary of Conclusions and Recommendations**

Before the Commission could consider means of improvement, it had to address the underlying theoretical issues. The ethical foundation of informed consent can be traced to the promotion of two values: personal well-being and self-determination. To ensure that these values are respected and enhanced, the Commission finds that patients who have the capacity to make decisions about their care must be permitted to do so voluntarily and must have all relevant information regarding their condition and alternative treatments, including possible benefits, risks, costs, other consequences, and significant uncertainties surrounding any of this information. This conclusion has several specific implications:

1. Although the informed consent doctrine has substantial foundations in law, it is essentially an ethical imperative.

2. Ethically valid consent is a process of shared decisionmaking based upon mutual respect and participation, not a ritual to be equated with reciting the contents of a form that details the risks of particular treatments.

3. Much of the scholarly literature and legal commentary about informed consent portrays it as a highly rational means of decisionmaking about health care matters, thereby suggesting that it may only be suitable for and applicable to well-educated, articulate, self-aware individuals. Whether this is what the legal doctrine was intended to be or what it has inadvertently become, it is a view the Commission unequivocally rejects. Although subcultures within American society differ in their views about autonomy and individual choice and about the etiology of illness and the roles of healers and patients, a survey conducted for the Commission found a universal desire for information, choice, and respectful communication about decisions. Informed consent must remain flexible, yet the process, as the Commission envisions it throughout this Report, is ethically required of health care practitioners in their relationships with all patients, not a luxury for a few.

4. Informed consent is rooted in the fundamental recognition—reflected in the legal presumption of competency—that adults are entitled to, accept or reject health care interventions on the basis of their own personal values and in furtherance of

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3 The Commission’s survey of the public broke down these responses on the basis of variables such as age, gender, race, education, and income.
their own personal goals. Nonetheless, patient choice is not absolute.

- Patients are not entitled to insist that health care practitioners furnish them services when to do so would violate either the bounds of acceptable practice or a professional’s own deeply held moral beliefs or would draw on a limited resource on which the patient has no binding claim.

- The fundamental values that informed consent is intended to promote—self-determination and patient well-being—both demand that alternative arrangements for health care decisionmaking be made for individuals who lack substantial capacity to make their own decisions. Respect for self-determination requires, however, that in the first instance individuals be deemed to have decisional capacity, which should not be treated as a hurdle to be surmounted in the vast majority of cases, and that incapacity be treated as a disqualifying factor in the small minority of cases.

- Decisionmaking capacity is specific to each particular decision. Although some people lack this capacity for all decisions, many are incapacitated in more limited ways and are capable of making some decisions but not others. The concept of capacity is best understood and applied in a functional manner. That is, the presence or absence of capacity does not depend on a person’s status or on the decision reached, but on that individual’s actual functioning in situations in which a decision about health care is to be made.

- Decisionmaking incapacity should be found to exist only when people lack the ability to make decisions that promote their well-being in conformity with their own previously expressed values and preferences.

- To the extent feasible people with no decisionmaking capacity should still be consulted about their own preferences out of respect for them as individuals.

(5) Health care providers should not ordinarily withhold unpleasant information simply because it is unpleasant. The ethical foundations of informed consent allow the withholding of information from patients only when they request that it be withheld or when it disclosure per se would cause substantial detriment to their well-being. Furthermore, the Commission found that most members of the public do not wish to have “bad news” withheld from them.

(6) Achieving the Commission’s vision of shared decisionmaking based on mutual respect is ultimately the responsibility of individual health care professionals. However, health care institutions such as hospitals and professional schools have
important roles to play in assisting health care professionals in this
obligation. The manner in which health care is provided in institutional
settings often results in a fragmentation of responsibility that may
neglect the human side of health care. To assist in guarding against this,
institutional health care providers should ensure that ultimately there is
one readily identifiable practitioner responsible for providing
information to a particular patient. Although pieces of information may
be provided by various people, there should be one individual officially
charged with responsibility for ensuring that all the necessary
information is communicated and that the patient’s wishes are known to
the treatment team.

(7) Patients should have access to the information they need to
help them understand their conditions and make treatment decisions. To
this end the Commission recommends that health care professionals and
institutions not only provide information but also assist patients who
request additional information to obtain it from relevant sources,
including hospital and public libraries.

(8) As cases arise and new legislation is contemplated, courts and
legislatures should reflect this view of ethically valid consent.
Nevertheless, the Commission does not look to legal reforms as the
primary means of bringing about changes in the relationship between
health care professionals and patients.

(9) The Commission finds that a number of relatively simple
changes in practice could facilitate patient participation in health care
decisionmaking. Several specific techniques—such as having patients
express, orally or in writing, their understanding of the treatment
consented to—deserve further study. Furthermore, additional societal
resources need to be committed to improving the human side of health
care, which has apparently deteriorated at the same time there have been
substantial gains in health care technology. The Department of Health
and Human Services, and especially the National Institutes of Health, is
an appropriate agency for the development of initiatives and the
evaluation of their efficacy in this area.

(10) Because health care professionals are responsible for ensuring
that patients can participate effectively in decisionmaking regarding
their care, educators have a responsibility to prepare physicians and
nurses to carry out this obligation. The Commission therefore concludes
that:

- Curricular innovations aimed at preparing health professionals
for a process of mutual decisionmaking with patients should be
continued and strengthened, with careful attention being paid to
the development of methods for evaluating the effectiveness of
such innovations.
Examinations and evaluations at the professional school and national levels should reflect the importance of these issues.

Serious attention should be paid to preparing health professionals for team practice in order to enhance patient participation and well-being.

(11) Family members are often of great assistance to patients in helping to understand information about their condition and in making decisions about treatment. The Commission recommends that health care institutions and professionals recognize this and judiciously attempt to involve family members in decisionmaking for patients, with due regard for the privacy of patients and for the possibilities for coercion that such a practice may entail.

(12) The Commission recognizes that its vision of health care decisionmaking may involve greater commitments of time on the part of health professionals. Because of the importance of shared decisionmaking based on mutual trust, not only for the promotion of patient well-being and self-determination but also for the therapeutic gains that can be realized, the Commission recommends that all medical and surgical interventions be thought of as including appropriate discussion with patients. Reimbursement to the professional should therefore take account of time spent in discussion rather than regarding it as a separate item for which additional payment is made.

(13) To protect the interests of patients who lack decisionmaking capacity and to ensure their well-being and self-determination, the Commission concludes that:

- Decisions made by others on patients’ behalf should, when possible, attempt to replicate the ones patients would make if they were capable of doing so. When this is not feasible, decisions by surrogates on behalf of patients must protect the patients’ best interests. Because such decisions are not instances of personal self-choice, limits may be placed on the range of acceptable decisions that surrogates make beyond those that apply when a person makes his or her own decisions.

- Health care institutions should adopt clear and explicit policies regarding how and by whom decisions are to be made for patients who cannot decide.

- Families, health care institutions, and professionals should work together to make health care decisions for patients who lack decisionmaking capacity. Recourse to courts should be reserved for the occasions when concerned parties are unable to resolve their disagreements over matters of substantial import, or when adjudication is clearly required by state law. Courts and legislatures should be cautious about
requiring judicial review of routine health care decisions for patients who lack capacity.

- Health care institutions should explore and evaluate various informal administrative arrangements, such as “ethics committees,” for review and consultation in nonroutine matters involving health care decisionmaking for those who cannot decide.

- As a means of preserving some self-determination for patients who no longer possess decisionmaking capacity, state courts and legislatures should consider making provision for advance directives through which people designate others to make health care decisions on their behalf and/or give instructions about their care.

The Commission acknowledges that the conclusions contained in this Report will not be simple to achieve. Even when patients and practitioners alike are sensitive to the goal of shared decisionmaking based on mutual respect, substantial barriers will still exist. Some of these obstacles, such as longstanding professional attitudes or difficulties in conveying medical information in ordinary language, are formidable but can be overcome if there is a will to do so. Others, such as the dependent condition of very sick patients or the ever-growing complexity and subspecialization of medicine, will have to be accommodated because they probably cannot be eliminated. Nonetheless, the Commission’s vision of informed consent still has value as a measuring stick against which actual performance may be judged and as a goal toward which all participants in health care decisionmaking can strive.

The Commission’s Process

The Commission’s inquiry into the ethical, legal, and practical aspects of informed consent in health care has drawn on the expertise of leading scholars from around the country, on the existing literature, on newly commissioned empirical studies, and on testimony from health care professionals, consumers, and commentators. The Commissioners devoted five hearings to informed consent and deliberated on the subject at three additional meetings.

Over the five days of hearings, testimony was heard on the components and functions of informed consent in health care, the relationships between patients and health care professionals, ways to increase patient participation in decisionmaking, the issue of patient competence and the roles of families in health care decisionmaking, and the education of physicians and nurses about informed consent issues. The witnesses

included physicians, nurses, health care administrators, representatives of consumer groups, and professors of sociology, philosophy, history, law, and public health. In addition, the Commission convened a panel of nursing experts from all over the country to discuss these issues.\footnote{For a complete list of witnesses and consultants, see the Addendum, pp. 189-91 infra.}

The Commission also contracted for three empirical studies in order to clarify certain aspects of informed consent in practice.\footnote{Reports from the commission’s own studies and a review of the empirical literature may be found in the Appendices, published as Volume Two of this Report. The focus of most of these studies has been on physicians, with very little attention paid to nurses and other health professionals who interact with patients. Where information about the roles of nonphysician professionals is available it has been included.} The results of these studies are used throughout the Report to illustrate key points and to measure the extent of discrepancy between current practice and the goals for communication and decisionmaking articulated by the Commission.

Although health care is clearly a diverse enterprise, the legal doctrine of informed consent seems to operate on the implicit assumption that medical care is only concerned with invasive procedures (typically surgery). To redress the narrowness of this focus, the first commissioned study sought to determine whether and how decisionmaking and communication between patients and health care professionals varied in different health care settings according to the nature of the illness and treatments under consideration, the types of health care providers, and patient characteristics. The study was conducted through interviews and observation under the direction of Professors Charles W. Lidz and Alan Meisel of the University of Pittsburgh and of the Western Psychiatric Institute and Clinic. Two researchers observed a surgical outpatient clinic and cardiology and surgery wards in a university hospital over a period of several weeks, throughout the day and evening. After noting the routines in each setting for several days, information was gathered on almost 200 cases. In 124 of these, the encounters between patients, physicians, and nurses were observed and recorded, and semistructured interviews were conducted with all who were involved in the decision at hand, often including family members.

Much has been written about the potentially negative consequences of providing patients with full information about their conditions and treatment, especially when it leads to refusals of “medically necessary” treatment, yet only scattered anecdotal evidence of such refusals exists. The Commission’s
other observational study sought to determine the frequency, nature, causes, and effects of treatment refusals. It found that treatment refusals were usually triggered by too little information rather than too much. The study was conducted in three stages by Drs. Paul S. Appelbaum and Loren H. Roth of the Western Psychiatric Institute and Clinic in Pittsburgh.

In the first stage, seven wards in four different medical hospitals were studied: a medicine, a surgery, and a neurology ward in a university-affiliated teaching hospital; a gynecology ward in a university-affiliated women’s hospital; an ophthalmology ward in a university-affiliated specialty hospital; and a medical and a surgical ward in a large community hospital. Each ward was visited for most of a day four times at one-week intervals, with each visit being held on a different day of the week. Information was provided by the nurse on all treatment refusals in the previous 24 hours; charts were reviewed and interviews conducted with the nurse most familiar with the case, with the staff member who elicited the refusal, and with the patient.

In the second stage, more in-depth study was made of the longitudinal course of refusals on the medical and surgical wards of the university-affiliated teaching hospital. Daily rounds were made for a three-week period of the surgery ward and for an eight-week period on the medicine ward. One observer made rounds with house staff and conducted interviews with physicians and nurses while the other observer interviewed patients. In the third stage, a case study approach was used to follow a number of cases of treatment refusal through the end of the patients’ hospitalization. Medical charts were reviewed daily, extensive initial interviews were conducted with patients and they were re-interviewed at least every other day, and in most cases a family member was interviewed as well.

In the third empirical study done for the Commission, Louis Harris and Associates conducted parallel national surveys of physicians and the public regarding their attitudes toward, experience with, and knowledge of informed consent, disclosure of information, and decisional authority in medical care. The questionnaires were designed by Commission staff in conjunction with John M. Boyle and Paul J. Brounstein of the Harris organization. Telephone interviews were conducted with representative national samples of 800 physicians and 1250 adults in the general public. According to the accepted principles for such polls, the sample sizes were sufficiently large to allow general statements to be made about the populations from which they were drawn with 95% confidence that estimates were correct to within 3%, and to permit analysis by subgroups with reasonable confidence. For the
public an “area probability sample” based on random-digit dialing was used, and for the physician survey a random sample was drawn of doctors who spend the majority of their time in direct care of adult patients. The response rate to both surveys was approximately 70%, which is well within (or above) the range of statistical acceptability for such surveys.

In analyzing the data from the surveys, many cross-tabulations were performed to see whether there were variations in attitudes or behavior by subgroups of the public or the physicians. For the public survey all questions concerning disclosure of information, decisionmaking, and knowledge of informed consent were examined in relation to the respondents’ age, gender, race, family income, education, self-reported health status, and health insurance status, whether or not the person had ever had a life-threatening illness, and the locale where he or she usually received medical care. For the physician sample all data were examined in relation to specialty, year of graduation from medical school, type of medical school attended (public, private, or foreign, and extent of research involvement), normal location of practice (office or hospital), the proportion of patients under the physician’s care who were seriously ill, the proportion who were poor, and the proportion who the physician thought could understand most aspects of their condition and treatment.

It is important to note that different empirical methods yield data that can differ in several ways. Surveys are based on self-reports about past or hypothetical situations and therefore may not be entirely accurate reflections of practice. Regarding health care, surveys are known to overstate the frequency with which information is disclosed and may present a rosier, more homogeneous picture of medical practice than an on-site investigation of the same population would. On the other hand, although studies by qualified neutral observers provide a truer picture of a piece of the real world, they often do not permit broad conclusions to be drawn. The results of

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7 The public sample was stratified by region of the country and within each region by size of the community. Use of random-digit dialing ensures that unlisted telephones are surveyed. Telephone surveys may slightly overrepresent the elderly and will generally significantly overrepresent females. To avoid this latter imbalance in the sample, a quota technique was used. In addition, all responses were weighted before doing the analyses to ensure that results reflected the total population rather than the population with telephones, thereby eliminating the slight bias that arises from the fact that about 2% of the U.S. population do not have telephones.

8 The physician sample was drawn according to study specifications by the American Medical Association, which maintains files of all physicians in the country and updates them monthly. This is the most reliable source of data on the total physician population in the country.
surveys are quantifiable, whereas observational studies largely yield qualitative results. The findings from these two types of studies are often complementary but they may also be divergent in some respects. (Differences between the Commission’s survey and the observational studies are noted throughout the Report where relevant.)

In general, the Commission’s surveys found that the relationship between physicians and patients is dynamic, that disclosures are extensive, that understanding and satisfaction are high, that decisionmaking is shared—and that patients expect their relations with physicians to have these characteristics. This was found to be especially true for office-based (as distinct from clinic- or hospital-based) settings, where doctors and patients are apparently able to establish a relationship over time. Furthermore, as might be expected, the public’s experience with the health care system appears to vary depending on whether the patient is young or old, in good or poor health, and well or poorly educated. In contrast, physicians’ self-reported behaviors and attitudes were relatively homogeneous. Even though the issue of informed consent has received a great deal of attention in the last decade, there was little variation among physicians by specialty, age, or nature of patients under their care.

The observational studies, on the other hand, found enormous variation in the patient-professional relationship and the decisionmaking process within various hospital settings. Such variation appears to be related to the structure in which care is delivered and the nature of patients’ conditions and treatments. In these studies, it was rare for the process described in this Report as ideal to be realized in practice. Because the observational studies were conducted principally in university-affiliated teaching hospitals the findings may not be representative of all hospital care. For example, in non-teaching hospitals patients are more likely to be cared for by fewer doctors (perhaps only one) than in teaching hospitals staffed with a large number of interns and residents, thus lessening the possibility that one doctor will mistakenly assume that another doctor has talked with a patient about treatment.

The Report

In addition to hearing witnesses, the Commission devoted portions of a number of meetings to its own deliberations on the study and helpful comments were received from former Commissioner Renee C. Fox, Professor of Sociology at the University of Pennsylvania, and Professor Jay Katz of Yale Law School. Drafts of this Report were discussed at several Commission meetings. On May 14, 1982, a draft was reviewed and the central conclusions were approved. On August 12,
1982, a final draft was discussed and approved, subject to editorial corrections, by the Commissioners who had reviewed the earlier draft and by four newly appointed members.

The Commission has divided this Report into four parts. The first traces the history of informed consent in the law and in medical practice and briefly sketches recent changes in the nature of health care and in society’s expectations for the patient-professional relationship. This is followed by a discussion of the values underlying informed consent. In Part Two, the ethical and legal obligations of health care professionals are discussed against a backdrop of what is known about actual practice. Part Three explores several means to bring goals and realities closer together. Attention is directed to innovative approaches in patient-professional communication and decisionmaking that appear to be practically as well as theoretically sound. Legal rules, along with professional attitudes and behavior as they are shaped by education and training, are examined for the roles they could play in providing patients with an effective basis for participation in decisionmaking. Recognizing that some people are unable to make some or all decisions on their own behalf, the Commission in Part Four of the Report sets forth principles and procedures for health care decisions that others must make for patients who lack decisionmaking capacity.