1. Making Health Care Decisions: The Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship

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 their own personal goals.

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Nevertheless, 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 its 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 the 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 long-standing 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.

2. Deciding to Forego Life-Sustaining Treatment: Ethical, Medical and Legal Issues in Treatment Decisions

1. The voluntary choice of a competent and informed patient should determine whether or not life-sustaining therapy will be undertaken, just as such choices provide the basis for other decisions about medical treatment. Health care institutions and professionals should try to enhance patients' abilities to make decisions on their own behalf and to promote understanding of the available treatment options.

2. Health care professionals serve patients best by maintaining a presumption in favor of sustaining life, while recognizing that competent patients are entitled to choose to forego any treatments, including those that sustain life.

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3. As in medical decisionmaking generally, some constraints on patients' decisions are justified.

—Health care professionals or institutions may decline to provide a particular option because that choice would violate their conscience or professional judgment, though in doing so they may not abandon a patient.

—Health care institutions may justifiably restrict the availability of certain options in order to use limited resources more effectively or to enhance equity in allocating them.

—Society may decide to limit the availability of certain options for care in order to advance equity or the general welfare, but such policies should not be applied initially nor especially forcefully to medical options that could sustain life.

—Information about the existence and justification of any of these constraints must be available to patients or their surrogates.

4. Governmental agencies, institutional providers of care, individual practitioners, and the general public should try to improve the medically beneficial options that are available to dying patients. Specific attention should be paid to making respectful, responsive, and competent care available for people who choose to forego life-sustaining therapy or for whom no such therapies are available.

5. Several distinctions are frequently made in deliberating about whether a choice that leads to an earlier death would be acceptable:

—The distinction between acting and omitting to act separates patients that deserve more scrutiny from those that are likely not to need it.

—The mere difference between acts and omissions never by itself determines what is morally acceptable. Acceptability turns on other morally significant considerations, such as the balance of harms and benefits likely, the duties of others to dying persons, the risks imposed on others in acting or refraining, and the certainty of outcome.

—The distinction between failing to initiate and stopping therapy—that is, withholding versus withdrawing treatment—is not itself of moral importance. A justification adequate for not commencing a treatment is also sufficient for ceasing it. Erecting a higher requirement for cessation might unjustifiably discourage vigorous initial attempts at treatment that sometimes succeed.

6. Achieving medically and morally appropriate decisions does not require changes in statutes concerning homicide or wrongful death, given appropriate prosecutorial discretion and judicial interpretation.
7. Primary responsibility for ensuring that morally justified processes of decisionmaking are followed lies with physicians. Health care institutions also have a responsibility:

- to ensure that there are appropriate procedures to enhance patients' competence,
- to provide for designation of surrogates,
- to guarantee that patients are adequately informed,
- to overcome the influence of dominant institutional biases,
- to provide review of decisionmaking, and
- to refer cases to the courts appropriately.

The Commission is not recommending that hospitals and other institutions take over decisions about patient care; there is no substitute for the dedication, compassion, and professional judgment of physicians.

Incompetent Patients Generally:

8. Physicians who make initial assessments of patients' competence and others who review these assessments should be responsible for judging whether a particular patient's decisionmaking abilities are sufficient to meet the demands of the specific decision at hand.

9. To protect the interests of patients who have insufficient capacity to make particular decisions and to ensure their well-being and self-determination:

- An appropriate surrogate, ordinarily a family member, should be named to make decisions for such patients. The decisions of surrogates should, when possible, attempt to replicate the ones that the patient would make if capable of doing so. When lack of evidence about the patient's wishes precludes this, decisions by surrogates should seek to protect the patient's best interests. Because such decisions are not instances of self-choice by the patient, the range of acceptable decisions by surrogates is sometimes not as broad as it would be for patients making decisions for themselves.

- The medical staff, along with the trustees and administrators of health care institutions, should explore and evaluate various formal and informal administrative arrangements for review and consultation, such as "ethics committees," particularly for decisions that have life-or-death consequences for incompetent patients.

- 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.
• Such advance directives provide a means of preserving some self-determination for patients who may lose decisionmaking capacity.

• Durable powers of attorney are preferable to "living wills" since they are more generally applicable and provide a better vehicle for patients to exercise self-determination, though experience with both is limited.

—Health care professionals and institutions should adopt clear, explicit, and publicly available policies regarding how and by whom decisions are to be made for patients who lack adequate decisionmaking capacity.

—Families, health care institutions, and professionals should work together to make decisions for patients who lack decisionmaking capacity. Recourse to the courts should be reserved for the occasions when adjudication is clearly required by state law or when concerned parties have disagreements that they cannot resolve over matters of substantial import. Courts and legislatures should be cautious about requiring judicial review of routine health care decisions for patients with inadequate decisionmaking capacity.

Patients with Permanent Loss of Consciousness:

10. Current understanding of brain functions allows a reliable diagnosis of permanent loss of consciousness for some patients.

Whether or not life-sustaining treatment is given is of much less importance to such patients than to others.

11. The decisions of patients' families should determine what sort of medical care permanently unconscious patients receive.

Other than requiring appropriate decisionmaking procedures for these patients, the law does not and should not require any particular therapies to be applied or continued, with the exception of basic nursing care that is needed to ensure dignified and respectful treatment of the patient.

12. Access to costly care for patients who have permanently lost consciousness may justifiably be restricted on the basis of resource use in two ways:

—by a physician or institution that otherwise would have to deny significantly beneficial care to another specific patient, or

—by legitimate mechanisms of policy formulation and application if and only if the provision of certain kinds of care to the patients were clearly causing serious inequities in the use of community resources.
Seriously Ill Newborns:

13. Parents should be the surrogates for a seriously ill newborn unless they are disqualified by decisionmaking incapacity, an unresolvable disagreement between them, or their choice of a course of action that is clearly against the infant's best interests.

14. Therapies expected to be futile for a seriously ill newborn need not be provided; parents, health care professionals and institutions, and reimbursements sources, however, should ensure the infant's comfort.

15. Within the constraints of equity and availability, infants should receive all therapies that are clearly beneficial to them. For example, an otherwise healthy Down Syndrome child whose life is threatened by a surgically correctable complication should receive the surgery because he or she would clearly benefit from it.

   —The concept of benefit necessarily makes reference to the context of the infant's present and future treatment, taking into account such matters as the level of biomedical knowledge and technology and the availability of services necessary for the child's treatment.

   —The dependence of benefit upon context underlines society's special obligation to provide necessary services for handicapped children and their families, which rests on the special ethical duties owed to newborns with undeserved disadvantages and on the general ethical duty of the community to ensure equitable access for all persons to an adequate level of health care.

16. Decisionmakers should have access to the most accurate and up-to-date information as they consider individual cases.

   —Physicians should obtain appropriate consultations and referrals.

   —The significance of the diagnoses and the prognoses under each treatment option must be conveyed to the parents (or other surrogates).

17. The medical staff, administrators, and trustees of each institution that provides care to seriously ill newborns should take the responsibility for ensuring good decisionmaking practices. Accrediting bodies may want to require that institutions have appropriate policies in this area.

   —An institution should have clear and explicit policies that require prospective or retrospective review of decisions when life-sustaining treatment for an infant might be foregone or when parents and providers disagree about the correct decision for an infant. Certain categories of clearly futile therapies could be explicitly excluded from review.
—The best interests of an infant should be pursued when those interests are clear.

—The policies should allow for the exercise of parental discretion when a child's interests are ambiguous.

—Decisions should be referred to public agencies (including courts) for review when necessary to determine whether parents should be disqualified as decisionmakers and, if so, who should decide the course of treatment that would be in the best interests of their child.

18. The legal system has various—though limited—roles in ensuring that seriously ill infants receive the correct care.

—Civil courts are ultimately the appropriate decisionmakers concerning the disqualification of parents as surrogates and the designation of surrogates to serve in their stead.

—Special statutes requiring providers to bring such cases to the attention of civil authorities do not seem warranted, since state laws already require providers to report cases of child abuse or neglect to social service agencies; nevertheless, educating providers about their responsibilities is important.

—Although criminal penalties should be available to punish serious errors, the ability of the criminal law to ensure good decisionmaking in individual cases is limited.

—Governmental agencies that reimburse for health care may insist that institutions have policies and procedures regarding decisionmaking, but using financial sanctions against institutions to punish an "incorrect" decision in a particular case is likely to be ineffective and to lead to excessively detailed regulations that would involve government reimbursement officials in bedside decisionmaking. Furthermore, such sanctions could actually penalize other patients and providers in an unjust way.

Cardiopulmonary Resuscitation:

19. A presumption favoring resuscitation of hospitalized patients in the event of unexpected cardiac arrest is justified.

20. A competent and informed patient or an incompetent patient's surrogate is entitled to decide with the attending physician that an order against resuscitation should be written in the chart. When cardiac arrest is likely, a patient (or a surrogate) should usually be informed and offered the chance specifically to decide for or against resuscitation.
21. Physicians have a duty to assess for each hospitalized patient whether resuscitation is likely, on balance, to benefit the patient, to fail to benefit, or to have uncertain effect.

—When a patient will not benefit from resuscitation, a decision not to resuscitate, with the consent of the patient or surrogate, is justified.

—When a physician's assessment conflicts with a competent patient's decision, further discussion and consultation are appropriate; ultimately the physician must follow the patient's decision or transfer responsibility for that patient to another physician.

—When a physician's assessment conflicts with that of an incompetent patient's surrogate,
  • further discussion,
  • consultation,
  • review by an institutional committee,
  • and, if necessary, judicial review should be sought.

22. To protect the interests of patients and their families, health care institutions should have explicit policies and procedures governing orders not to resuscitate, and accrediting bodies should require such policies.

—Such policies should require that orders not to resuscitate be in written form and that they delineate who has the authority both to write such orders and to stop a resuscitation effort in progress.

—Federal agencies responsible for the direct provision of patient care (such as the Veterans Administration, the Public Health Service, and the Department of Defense) should ensure that their health care facilities adopt appropriate policies.

23. The entry of an order not to resuscitate holds no necessary implications for any other therapeutic decisions, and the level or extent of health care that will be reimbursed under public or private insurance programs should never be linked to such orders.

24. The education of health care professionals should ensure that they know how to help patients and family make ethically justified decisions for or against resuscitation; those responsible for professional licensure and certification may want to assess knowledge in these areas.
3. Securing Access to Health Care: The Ethical Implications of Differences in the Availability of Health Services

In this Report, the President's Commission does not propose any new policy initiatives, for its mandate lies in ethics not in health policy development. But it has tried to provide a framework within which debates about health policy might take place, and on the basis of which policymakers can ascertain whether some proposals do a better job than others of securing health care on an equitable basis.

In 1952, the President's Commission on the Health Needs of the Nation concluded that "access to the means for the attainment and preservation of health is a basic human right." Instead of speaking in terms of "rights," however, the current Commission believes its conclusions are better expressed in terms of "ethical obligations."

The Commission concludes that society has an ethical obligation to ensure equitable access to health care for all. This obligation rests on the special importance of health care: its role in relieving suffering, preventing premature death, restoring functioning, increasing opportunity, providing information about an individual's condition, and giving evidence of mutual empathy and compassion. Furthermore, although life-style and the environment can affect health status, differences in the need for health care are for the most part undeserved and not within an individual's control.

In speaking of society, the Commission uses the term in its broadest sense to mean the collective American community. The community is made up of individuals who are in turn members of many other, overlapping groups, both public and private: local, state, regional, and national units; professional and workplace organizations; religious, educational, and charitable institutions; and family, kinship, and ethnic groups. All these entities play a role in discharging societal obligations.

The societal obligation is balanced by individual obligations. Individuals ought to pay a fair share of the cost of their own health care and take reasonable steps to provide for such care when they can do so without excessive burdens. Nevertheless, the origins of health needs are too complex, and their manifestation too acute and severe, to permit care to be regularly denied on the grounds that individuals are solely responsible for their own health.

Equitable access to health care requires that all citizens be able to secure an adequate level of care without excessive burdens. Discussions of a right to health care have frequently been premised on offering patients access to all

beneficial care, to all care that others are receiving, or to all that they need—or want. By creating impossible demands on society’s resources for health care, such formulations have risked negating the entire notion of a moral obligation to secure care for those who lack it. In their place, the Commission proposes a standard of "an adequate level of care," which should be thought of as a floor below which no one ought to fall, not a ceiling above which no one may rise.

A determination of this level will take into account the value of various types of health care in relation to each other as well as the value of health care in relation to other important goods for which societal resources are needed. Consequently, changes in the availability of resources, in the effectiveness of different forms of health care, or in society’s priorities may result in a revision of what is considered "adequate."

Equitable access also means that the burdens borne by individuals in obtaining adequate care (the financial impact of the cost of care, travel to the health care provider, and so forth) ought not to be excessive or to fall disproportionately on particular individuals.

When equity occurs through the operation of private forces, there is no need for government involvement, but the ultimate responsibility for ensuring that society’s obligation is met, through a combination of public and private arrangements, rests with the Federal government. Private health care providers and insurers, charitable bodies, and local and state governments all have roles to play in the health care system in the United States. Yet the Federal government has the ultimate responsibility for seeing that health care is available to all when the market, private charity, and government efforts at the state and local level are insufficient in achieving equity.

The cost of achieving equitable access to health care ought to be shared fairly. The cost of securing health care for those unable to pay ought to be spread equitably at the national level and not allowed to fall more heavily on the shoulders of particular practitioners, institutions, or residents of different localities. In generating the resources needed to achieve equity of access, those with greater financial resources should shoulder a greater proportion of the costs. Also, priority in the use of public subsidies should be given to achieving equitable access for all before government resources are devoted to securing more care for people who already receive an adequate level.[9]

Efforts to contain rising health care costs are important but should not focus on limiting the attainment of equitable access for the least well served portion of the public. The achievement of equitable access is an obligation of sufficient moral urgency to warrant devoting the necessary resources to it. However, the nature of the task means that it will not be achieved immediately.

5. Although the Commission does not endorse devoting public resources to individuals who already receive adequate care, exceptions arise for particular groups with special ethical claims, such as soldiers injured in combat, to whom the nation owes a special debt of gratitude.
While striving to meet this ethical obligation, society may also engage in efforts to contain health costs—efforts that themselves are likely to be difficult and time-consuming. Indeed, the Commission recognizes that efforts to rein in currently escalating health care costs have an ethical aspect because the call for adequate health care for all may not be heeded until such efforts are undertaken. If the nation concludes that too much is being spent on health care, it is appropriate to eliminate expenditures that are wasteful or that do not produce benefits comparable to those that would flow from alternate uses of these funds. But measures designed to contain health care costs that exacerbate existing inequities or impede the achievement of equity are unacceptable from a moral standpoint. Moreover, they are unlikely by themselves to be successful since they will probably lead to a shifting of costs to other entities, rather than to a reduction of total expenditures.