Informing Patients and Disclosure of Information

October 3, 2000

Contacts: V. Aita, PhD, R. Anderson, JD, MS

Objectives:

1. Identify the main ethical and legal principles of professional practice regarding informed consent and disclosure to the patient.
2. Discuss the major components or elements of informed consent as described by Holleman in the required reading.
3. State the circumstances in which formal consent may be ethically and legally omitted.
4. Define the following terms as they apply to the principle of informed consent:

   - Decision-making capacity (competence-archaic)
   - Autonomy
   - Paternalism
   - Standards for disclosure
   - Informed Consent
   - Implied Consent
   - Presumed consent
   - Waived Consent
   - Therapeutic privilege
   - Surrogate/proxy
   - Substituted judgment
   - Best- interest standard

5. Review and discuss cases in which informed consent and disclosure are at issue.

Required reading:
Holleman, Medical Ethics, pp. 282-290 (On reserve in McGoogan Library) and this handout.

Informed Consent and Disclosure Outline:

The ethical principle of **beneficence** compels physicians to protect a patient from the harm he may endure if unable to make health care decisions for himself.

The ethical principle of **nonmaleficence** or **do no harm**, compels physicians to act in the best interest of patients, prohibiting them from providing ineffective therapies or acting out of self interest.

The ethical principle of **autonomy** compels physicians to respect every capable adult patient’s right to determine what shall be done with his/her body.

Parallel legal principles include:

**Self-determination**, **liberty** and **privacy** are constitutionally protected principles.
Protection of bodily integrity means the patient has a right to control what happens to his/her body. By not obtaining a patient’s informed consent the physician may be liable for battery, the non-consensual touching of another person. Fiduciary obligation imposes a higher duty of care on those with specialized information in a professional relationship.

If a physician fails to inform the patient of his/her condition, the benefits of treatment/non-treatment, and the risks of treatment/non-treatment, he/she may be liable for negligence, the breach of a duty to a patient.

Informed consent requirements represent a contract between physician and patient recognizing and respecting the patient’s right to self-determination.

Legal precedents:

Schloendorff v. Society of New York Hospital. [105 NE 92 (NY, 1914)].
Salgo v. Leland Stanford, Jr. University Board of Trustees [317 P 2d 170 (CA 1957)].
Truman v. Thomas [611 P 2d 902 (CA 1980)].

Standards for disclosure:

Locality or reasonable provider standards: As in the Nebraska Hospital-Medical Liability Act. Informed consent shall mean consent to a procedure based on information which would ordinarily be provided to the patient under like circumstances by health care providers engaged in a similar practice in the locality or in similar localities. Failure to obtain informed consent shall include failure to obtain any express or implied consent for any operation, treatment, or procedure in a case in which a reasonably prudent health care provider in the community or similar communities would have obtained an express or implied consent for such operation, treatment, or procedure under similar circumstances.

Reasonable patient standard: As recommended by American Medical Association Code of Ethics. The patient’s right of self-decision can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The patient should make his or her own determination on treatment. The physician’s obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient’s care and to make recommendations for management in accord with good medical practice . . . . (AMA Code of Ethics, section, 8:08)

Caveat: Standards are fluid, and subject to specific practice, specialties, locality, and era.

Decision-making capacity:

The notion of informed consent pivots on the patient’s ability to make a choice authorizing or refusing treatment after being given the information needed to understand the consequences of that choice for him or herself. The ability to make such a choice is called decision-making capacity.
Elements of informed consent:

Nature of condition:
What is it? What caused it? Is it contagious? Is there a hereditary link? What is the expected progression of the condition (how will the condition affect physical well-being, work, life, future, family)? Is it life threatening?

Treatment options:

Benefits of each treatment
Risks of each treatment
Discomforts/side effects of each treatment
Costs of each treatment
Benefits, risks, discomforts, side effects of non-treatment:

Truman v. Thomas, 1980 held that patients must be informed of risks involved in not undergoing treatment.

Recommendation of physician based on best medical judgment.

What is valid consent or refusal?

Proper information has been disclosed to the patient
The patient is able to make a voluntary, reasoned decision based on facts, values
Patient can communicate a preference
Patient maintains a consistent stance vis-à-vis treatment

Exceptions/variations:

Implied consent (presenting for common, trivial-risk procedures)
Presumed consent (emergency conditions; incapacity)
Proxy or Substituted consent (minors, incapacity)
Waived consent (express request not to know)
Therapeutic privilege (not in patient s best interest to know)

Challenges of informed consent:

Time constraints
Language barriers/failure of patient and/or physician to communicate effectively
Practical judgments of physician about patient s background, understanding, logical thought processes, awareness of consequences
Physician conflict with patient s belief system, values
Patient s compromised decision-making capacity
Problems with substituted judgement (surrogate determination of patient s best interests) and Advance Directives: Living Will, Durable Power of Attorney for Health Care.
Paternalism
Patient representatives:

A person who cannot effectively make, or communicate, health care decisions must be represented by someone else. Most commonly, parents represent their children until the age of majority (19 in Nebraska). After the age of majority, people are presumed capable of caring for their own affairs unless otherwise demonstrated. (The old term, incompetence has been abandoned in favor of incapacity in the Nebraska statutes, and a similar shift of vocabulary is warranted in medicine.) An individual who is found by the courts to be incapable of managing some aspect of his or her affairs is assigned a legal guardian. The guardian may have complete decisional authority for the ward, or may be limited to a particular area (e.g. financial, medical, etc.). Here is the order of priority for assignment of guardians by the court (Neb. Rev. Stat. 30-2627):

1) the nominee of the incapacitated person, through a power of attorney or durable power of attorney (documents which appoint a representative to assume decisional authority)
2) the spouse of the incapacitated person
3) an adult child of the incapacitated person
4) a parent of the incapacitated person or the appointee of a deceased parent
5) any relative with whom the incapacitated person has resided for the past 6 months
6) the nominee of the person caring for or paying benefits for the incapacitated person

The court is to consider the wishes of the ward and, acting in the best interest of the ward, may pass over a person with higher priority to appoint a person of lesser priority or no priority.

In the medical setting, the same order of priority is reasonable in seeking substituted judgment during temporary incapacity. Permanent incapacity should prompt discussion of a formal appointment of a guardian, unless the patient has an advance directive appointing a representative who is willing and able to serve.

In general, one exercises substituted judgment (attempting to discern and honor what the incapacitated person would have wanted) for people who once had decisional authority but lack it now. One exercises the best interests test (attempting to discern what does the most good and the least harm for the person) for people who never had decisional authority, or when the preferences of the individual are not known.

Panel discussion of case:

Mrs. H. is an 84-year-old patient who was admitted to the hospital with an ileus (bowel obstruction), a urinary tract infection, and a left hip replacement. The patient is married, but has been estranged from her husband for the past 25 years. The patient’s only daughter died a number of years ago, but her three young adult grandchildren live with her and take care of her in her home. Mrs. H. lost decision-making capacity during the latter part of this hospitalization, but she had been aware and lucid earlier during the admission. Because of her declining status, the grandchildren made the decision by consensus, with the support of physician staff, to instate a Do Not Resuscitate
Order. The grandchildren had also been wrestling with the decision whether or not to insert a feeding tube directly into the patient’s stomach, but because they couldn’t agree, they decided not to. The grandchildren also struggled with the decision of whether or not to take the patient home and care for her there—a preference the patient had made clear on numerous occasions in the past—or to discharge the patient to a nursing home. Physicians and nurses caring for the patient tended to favor the latter. Residents caring for the patient suspected that the care the grandchildren provided was less than optimal and were concerned about the possibility of elder neglect and even abuse. The patient’s husband was rarely present and did not contest the grandchildren’s decisions.

Questions for discussion:

1) Who should serve as Mrs. H.’s surrogate decision-maker?
2) What is the role of a surrogate decision-maker?
3) How should a physician interpret this patient’s previously stated preferences (i.e., the patient would want to go home) when the home environment seems inadequate to the care staff?
4) Must physicians strictly observe hospital established order of proxy when clinical judgment indicates that may not be in the best interest of the patient?