

## Principles of Biomedical Ethics

➤ Page numbers reference Garrett et. al., Health Care Ethics. Prentice Hall, 2nd Edition, 1993, *unless otherwise indicated*.

Additional References:

1. Beauchamp and Childress, Principles of Biomedical Ethics, Fourth Edition. Oxford. 1994.
2. Engelhardt, H. Tristram Oxford: The Foundations of Bioethics, second edition, Oxford. 1996
3. Hall and Ellman, Health Care Law and Ethics, West. 1990.
4. Junkerman and Schiedermaier, Practical Ethics for Students, Interns, and Residents. University Publishing Group, 1998
5. American Medical Association Code of Medical Ethics, 1996
6. American College of Physicians Ethics Manual, Third Edition, 1993.

[These texts are available at the Erlanger Hospital Medical Library].

A standard approach to biomedical ethics, developed by Beauchamp and Childress in Principles of Biomedical Ethics, resolves ethical issues in terms of four ethical principles:

**Autonomy** [pages 1-6]

**Beneficence & non-maleficence** [pages 6-10]

**Justice** [pages 10-12]

Each of which need to be weighed and balanced in determining an optimal course of action.

All of these principles require a *conversation* about the needs and desires of the patient or, in the case of justice, members of community. The principles are intended to guide. In the case of autonomy, we are required to determine the wishes of the patient in order to protect his or her autonomy. In the case of beneficence and non-maleficence, we are required to determine the patient's views of what does and does not count as goods to be pursued or harms to be avoided. In the case of justice, we are required to follow due process in order to determine just limits on health care that will be generally accepted.

The demand for conversation arises out of what Engelhardt sees as the result of the break down of any traditional consensus about moral and religious goods. In particular, he argues that in the post-modern period, we no longer accept the possibility of constructing a content-full account of the human good. We engage one another, consequently, as moral strangers, who need to negotiate moral arrangements. Those negotiations are governed by the principles of autonomy (he calls it permission) and beneficence, but even in the case of beneficence we cannot presume a general agreement about human goods and their ranking. Engelhardt argues that the traditional distinctions used to distinguish moral categories of treatment assume a vision of the good that is not available to us.

For better or for worse, health care practitioners find themselves in a situation where they need to become moral negotiators with moral strangers.

The bioethical principles below are designed to be helpful guides to carrying out negotiations and conversations about treatment options.

### **Autonomy:**

#### **1. What is the moral basis of the principle of patient autonomy or self-rule?**

- The principle of autonomy is based on the **Principle of Respect for Persons**, which holds that individual persons have right to make their own choices and develop their own life plan (Garrett, 28). (See also American College of Physicians Ethics Manual, 2, 15.)
- In a health care setting, the principle of autonomy translates into the principle of informed consent: You shall not treat a patient without the informed consent of the patient or his or her lawful surrogate, except in narrowly defined exceptions [see item 8 below] (Garrett, 29).
- In order to affirm autonomy, every effort must be made to discuss treatment preferences with patients and to document them in the patients' charts.

#### **2. What are the requirements for informed consent?**

- The **patient or surrogate** must:
  - be **competent**, that is, capable of understanding consequences of the consent and capable making a free choice.
  - be free from coercion or **undue influence**.
- The **health care provider** must:
  - provide and make **understandable necessary information** for making a free, intelligent treatment decision and must make sure that the patient or surrogate understands the information (30).
  - The only way to know if the patient understands the information is through **reflective conversation** with the health care provider.
  - The health care provider must **recommend** what he or she takes to be the optimal option and is **free to persuade**, without pressuring, the patient of this option (37).
  - Note that legal informed consent, e.g. signing a waiver, does not meet the moral standards of informed consent.

#### **3. What is required for a person to be competent?**

- One must presume that **adult** patients are competent.
- Competence to make medical decisions requires that the patient know that he or she is **authorizing medical treatment** and is able to understand effects of treatment, options in terms of health, life, lifestyle, religious beliefs, values, family friends, and all other factors bearing on treatment decision (31). (See also American College of Physicians Ethics Manual, 8.)

- There is no easy way to determine incompetence except through the requirement that the health care provider spend time getting to know the patient and the patient's mind and understanding (33).
- **Factors to consider:** inability to express preference, inability to understand one's situation and its consequences, inability to understand relevant information, inability to give a reason, inability to give a rational reason, inability to give risk/benefit reasons, inability to reach a reasonable decision (Beauchamp and Childress, 137).
- The relevant competence is competence to make the specific treatment decision at hand (Beauchamp and Childress, 135).
- The fact that the patient has values different from the health care provider does not by itself prove the patient incompetent (31).
- Standards for competence may be set higher in cases where the consequences are more substantial (Hall and Fellman, 264 and Beauchamp and Childress, 138).

#### 4. What should one do in case a patient is incompetent?

- First, the medical practitioner must consult the **patient's living will** if there is one.
- Second, if there is no living will or the living will provides no clear guidance, the medical practitioner must consult a surrogate decision maker: either one designated by a durable **power of attorney**, or a **family member**, in order of priority: healthcare durable power of attorney, or guardian; spouse; children of legal age; parents; siblings of legal age; grandparents; grandchildren of legal age; other relative, close friend, or caregiver. (See American College of Physicians Ethics Manual, 8 and Erlanger Hospital's DNR Policy #8316.011).

#### 5. What principles should govern decision-making once a patient is no longer competent?

- There is a hierarchy of approaches once one cannot determine the patient's wishes directly.
  - In so far as possible, in order not to violate the patient's autonomy, a physician must honor known prior expressed preferences of the patient (Beauchamp and Childress, 173 and American College of Physicians Ethics Manual, 7). Evidence of **known prior preferences** can be determined by consulting the patient's chart and by consulting people who know the patient and his or her preferences.
  - If the physician does not know the prior expressed preferences about a specific treatment, the **surrogate for health care decision-making may make a substituted judgment** and determine what the patient would prefer, given the facts of his or her case where he or she competent to decide. Such estimates require substantial information about the

## SECTION 5

patient's views and wishes and must not simply reflect the preferences or interests of the physician or surrogate (46; Beauchamp and Childress, 171 and American College of Physicians Ethics Manual, 7).

- If there is no sufficient basis to make a substituted judgment, then the physician or surrogate must decide based on his or her judgment about what would be in the **best interest of the patient** (Beauchamp and Childress, 178 and American College of Physicians Ethics Manual, 7). Estimates of best interest are based on what a rational, normal person would prefer, not just on what the physician or surrogate prefers.
- In cases in which the attending physician, nurse, patient, surrogate, patient family or other legitimately involved persons disagree about whether treatment would be in a patient's best interest, a meeting should be called in which all such parties have a chance to exchange information and views. Often the hospital chaplain or family priest, minister, or rabbi can be of help in coming to agreement.
- In cases where such a meeting does not result in agreement, interested parties should consult the institutional ethics committee.
- When a surrogate or physician is acting against the expressed preferences or best interest of the patient and consultation with an institutional ethics committee fails to bring a resolution of the disagreement, the courts can be consulted to order treatment or appoint a conservator.

### 6. How much disclosure is required in order to satisfy the demand for informed consent?

There are two different possible standards for full disclosure:

- A. The *prudent person rule*
- B. The **subjective substantial disclosure rule** (35-36)

The *prudent person rule* requires that the patient knows and understands:

1. The diagnosis
2. The nature and purpose of the proposed treatment.
3. The known risks and consequences of the proposed treatment, excluding those too remote and improbable or too well known to bear on the treatment decision.
4. Included should be the doctor's and hospital's success and failure rates with the proposed treatment and "judgment errors made in the course of care if such information affects the care of the patient" (American College of Physicians Ethics Manual, 9)
5. The benefits expected of the proposed treatment and the likelihood of their being realized.
6. All alternative treatments, with all the information for them mentioned in 3 and 4 above.
7. The prognosis if no treatment is given.

## SECTION 5

8. All costs and burdens of the treatment and of the alternatives mentioned in 5 above.

The ***subjective substantial disclosure rule*** requires that the health care provider describe to the patient everything material or important to that particular patient, that is, all information that could alter the patient's reasoning about the treatment, given his or her principles, beliefs, and values. *Note that this rule invalidates any blanket disclosure policy.* For example, a blanket disclosure policy of not informing patient's of improbable risks violates, or may violate this rule. Note also that the parallel requirement of informed consent in medical research demands that "no fact should be concealed that might cause the particular patient, or a reasonably prudent person, to refuse participation in the study" (263). (See also Beauchamp and Childress, 156).

### **7. Are there exceptions to the requirement to seek explicit informed consent?**

A. Implied consent- When consent is implied and procedures are not risky or invasive (American College of Physicians Ethics Manual, 7).

B. Therapeutic privilege- If there is a reason to believe that information given to a specific patient will result in an adverse effect on the patient's condition or health, information may be withheld. (See AMA Code, 8.08 and American College of Physicians Ethics Manual, 8) But note that studies show that health care providers misestimate their patients adverse responses. So therapeutic privilege is almost never justified (Beauchamp and Childress, 151).

C. Emergencies- If the patient is not competent and no surrogate is available and his or her advance wishes are not known and there is danger to life or danger of serious impairment to health, and immediate treatment is necessary to avert these dangers, then the obligation to seek informed consent is waived (39). (See AMA Code, 8.08 and American College of Physicians Ethics Manual, 7).

D. In a case in which the patient's capacity to reason and sense of values may be affected by his or her illness or some transitory mood and treatment would bring about an irreversible state, the health care provider may be justified in postponing treatment even if the patient wants it, based on an appeal to beneficence (Hall-Ellman, 267).

### **8. When is violating informed consent clearly unjustified?**

- Non-emergencies with incompetent patients. If there is no surrogate available and no living will, Garrett argues that the courts should be used to appoint a guardian (40), but Beauchamp and Childress argue that "a hospital, a physician, or family member may justifiably be placed in a decision making role or go before a court or other authority to seek resolution of the issues before a decision is implemented" (170).

- As a form of manipulation when the health care provider wishes to influence a decision by withholding information (38).

**9. When is overriding a patient's autonomous preference, or medical paternalism, justified?**

- *Medical paternalism* is acting without consent or overriding a person's wishes, wants, or actions, in order to benefit the patient or prevent harm to him or her (43).
- *Strong paternalism*, the overriding of a competent patient's explicit wishes, is generally rejected since it violates autonomy; falsely presumes independent knowledge of what is best for the patient; and falsely presuppose that there is a clear, objective set of values governing such decisions (44). (See AMA Code, 8.08.) As a result, patients have the right to refuse treatment (48). (See also AMA Code, 2.20 and American College of Physicians Ethics Manual, 15). The right to refuse treatment might be limited, however, in court by appeal to parental obligations or in extreme cases suicide laws (Hall-Ellman, 268 ff.), or in case the autonomy interest at stake is weak in comparison to the benefit to the patient: raising bed rails against a competent patient's wishes (Beauchamp and Childress, 282-83). This sort of exception would not work for a Jehovah's Witnesses refusing blood transfusion, since his or her autonomy interest would be strong.
- *Weak paternalism*, acting for the benefit of an incompetent patient, is justified in some cases in order to restore that person's competence, or in order to protect a confused patient from harm (45).

**10. What is the role of the Ethics Committee in protecting a patient's autonomy?**

The Ethics Committee should act primarily as a guardian of patient's rights and may be legally liable for recommendations (42).

**Beneficence and Non-maleficence:**

**1. What are these two principles and how are they related to one another?**

The principle of *beneficence* requires us, other things being equal, to do good, or what will further the patient's interest. The principle of *non-maleficence* requires us, other things being equal; to avoid harm to the patient, or what would be against the patient's interests.

Both principles rest on the fundamental importance of what is in the patient's interest. The first is the positive requirement to further the

patient's interest. The second is the requirement to refrain from doing what damages the patient's interest.

## 2. Aren't these principles the same? Isn't avoiding harm just one instance of benefiting a person?

The difference between the principles rests on the *character of the avoidance of positive harm and the demand for positive benefit*. The following secondary principles come under the principle of **non-maleficence**:

- Do not kill.
  - Do not cause needless pain.
  - Do not incapacitate others (Beauchamp and Childress, 194).
- ⇒ The important point to notice is that each of these principles can be met by *doing nothing*.

The following are secondary principles falling under the principle of **beneficence**:

- Prevent the infliction of needless pain.
- Prevent killing.
- Prevent incapacitating others.

In a particular instance, for example, of standing by and watching a person who is undergoing a procedure done by an assistant, I might satisfy the principle of non-maleficence by not causing needless pain, but violate the principle of beneficence by not preventing pain.

## 3. Do these principles require us to do all good and avoid all evil?

Both principles are qualified by the recognition that there are limits on what each person can do and that many treatment options are mixed, containing both chance of benefit and risk of harm. Spelled out fully, the principle of beneficence means that unless there is a sufficient reason not to, one has an obligation to do those acts that are likely to do more good than harm. The principle of non-maleficence means that unless there is a sufficient reason not to, one has an obligation not to do those acts that likely to produce more harm than good (Garrett et. al., 54-55).

## 4. How do these principles help us to make treatment decisions?

There is no way to use these principles to make decisions in the abstract. A practitioner must take into consideration various social agreements about what is in the interest of the patient, the standard of care within the profession, what the patient or his or her surrogate, consistent with standards of informed consent, agrees to.

With these qualifications in mind, we can assert that the least controversial treatment is one that accords with the interest of the

patient, is consistent with the standard of care within the profession, is agreed to by the patient, consistent with his or her informed consent, and satisfies both the principle of non maleficence and beneficence.

**5. What happens if not all these conditions are met?**

There is no general answer to this question, but typically the following rules of thumb are reasonable:

- A. When there is a conflict between the two principles, the principle of non-maleficence trumps the principle of beneficence. For example, if harvesting two good kidneys from an almost but not quite dead man helps two patients on dialysis, we should not harvest the organs since doing so would violate the principle of non maleficence by harming the potential donor. Two good outcomes do not override the demand that we not harm patients (Beauchamp and Childress, 191).
- B. When the doctor offers a treatment and recommends it, the patient's informed decision against treatment trumps the medical practitioner's offer of treatment whether under the category of obligatory treatment (medically indicated) or optional (Garrett et. al., 57).
- C. When a procedure has both harmful and beneficial outcomes,
  - a treatment that is likely to bring significant benefit with only small risk of limited harm is obligatory (medically indicated) within the limits of informed consent. (Proportionally the treatment produces more good than harm.)
  - a treatment that is most likely to bring about significant harm with only small chance significant benefit, is obligatory not to offer (medically not indicated) even if the patient wants it. (Proportionally the treatment produces more harm than good.)
  - a treatment that is not likely to produce significantly more benefit than harm is optional (neither medically indicated nor medically not indicated). (Beauchamp and Childress, 211-15, use the language of obligation, and Garrett et. al., 58-61, use the language of medical indication.) (Proportionally the harm and good are equivalent.)

**6. How does one tell what benefits and harms the patient? Can one consider quality of life?**

Some ethicists argue that medical practitioners ought to distinguish questions of medical benefit, which fall within the expertise of medical practitioners, from questions of quality of life. For an example, see the discussion of Paul Ramsey's views (Beauchamp and Childress, 216).

Other ethicists argue that there is no clear and distinct way to make judgments about medical benefit without making estimates of quality of



life. (Note that Beauchamp and Childress and Garrett et. al., 150-51, fall into this group.)

It is also worth noting that the AMA recognizes the legitimacy of considering questions of quality of life when making treatment decisions (AMA Code, 2.17).

**7. Does appeal to the quality of life mean that we can decide not to treat a mentally retarded or severely disabled neonate who might medically benefit from treatment? *In short 'no.'***

The standard view is that mental retardation or disability ought not be a decisive factors by themselves in determining treatment ( Garrett et. al., 63-64). On the Beauchamp and Childress view, mental retardation is not a legitimate factor either (216). For them, which treatments benefit a patient must be assessed from within the limits of the viewpoint of the patient. The fact of mental retardation or disability of a person gives one the horizon from which to produce quality of life estimates for the person but does not by itself eliminate quality from that person's life. So if from the vantage point of the patient, he or she can lead a life of some satisfaction even if it departs from a normal life, that is sufficient to generate interests in terms of which benefits and harms to the patient can be established.

**8. Is financial or emotional burden to the family relevant to determining how these principles can be used to categorize treatments? *In short, 'no.'***

⇒ The fundamental question is always what is in the interest of the patient, not what is in the interest of the family.

**9. How then ought one to determine what will count as quality of life for a particular patient and so the treatment that provides a medical benefit?**

- ❖ For patients who are competent, one ought normally to give most weight to what the patient sees as beneficial (Beauchamp and Childress, 212).
- ❖ For patients who are not competent, one should consult his or her living will or his or her surrogate. (See Principle of Autonomy, 4 and 5 above.)

Given the extensive disagreement in our society over questions of what makes life valuable, it is necessary to foster communication between disagreeing parties that can resolve conflicts.



The formal principle of justice requires that a health care practitioners and society in general treat equal cases equally. For example, two patients with the same medical need ought not be treated differently (Beauchamp and Childress, 329). This principle, though crucial, does not tell us what we need or which needs are most important.

**3. How are needs to be understood and what is their significance for fair distribution?**

- ❖ Need is the basis for the individual's claim to any basic good.
- ❖ Even though need may be difficult to define precisely in every case, especially so since it may have its source in either the individual or in his social situation, disregarding individual's needs amounts to neglect.

**4. What factors contribute to determining medical need?**

- Medical need should be determined in terms of the following criteria: likely benefit to the patient, urgency of need, change in quality of life, duration of benefit.
- Non-medical criteria for limits should not be used: ability to pay, social worth, obstacles to treatment, patient contribution to illness, and use of past resources (AMA Code, 2.03).

There are three different levels in which questions of social justice are raised: national, institutional, and individual.

**5. How are priorities to be determined at the *national level*?**

- Medical need must be determined.
- Costs of basic goods must be considered when dealing with scarce resources.
- No society can provide everything that everyone needs, let alone what everyone wants.
- Economic considerations must be acknowledged to prevent destroying the economy.

Beyond this, various proposals, all in some way problematic, have been offered (See Garrett et. al., 85-90).

**6. Given the difficulty of determining an adequate account of fair distribution, how should we proceed?**

One approach, a procedural one, emphasizes the need for due process and specifically an open discussion of rationing policies. When we cannot know what is right with the help of a theory, we ought to insure that the acceptance of rationing limits proceeds through an open process that produces, as a result, a general consensus.

Failure to follow due process in the course of establishing limits to health care will result in procedural unfairness.

**7. How are priorities to be determined at the *institutional level*?**

Allocation at the institutional level is often conceived on the model of medical triage, where triage is, in the military, the process of sorting sick and wounded soldiers on the basis of urgency and type of problem for proper treatment. In triage, the good of the group is given precedence over the good of the individual. Nonetheless, triage disregards everything but the medical indications and the needs of the individual patients in determining which patients to treat first. The triage model is appropriate, for example, in situations of scarcity of beds in an ICU unit. The problem facing the staff in such a case is how to bring about the greatest good in this situation of scarcity. Decisions should be based on medical need. (See 3 above.)

Even though health care providers ought to attempt to insure that patients get what they need (See 2 above), government-owned and operated hospitals, which should be open to all, ought to grant priority to the economically disadvantaged on the basis of medical need paid for out of general funds. Here the assumption that those with health insurance or sufficient wealth can obtain services elsewhere.

In addition, academic medical centers often give preference to cases which increase knowledge in the field, an allocation on the basis of potential contribution of society rather than on the basis of patient need alone.

**8. How is allocation to be determined at the individual, health care provider-patient level?**

Health care practitioners ought not to ration at the bedside (AMA Code, 2.03, American College of Physicians Ethics Manual, 28). Such rationing is not a part of the health care provider's traditional role and will inevitably violate the formal principle of justice and the demand for due process in establishing rationing policies.

The health care provider has a responsibility to be an advocate for the patient within the institutional setting in which he or she practices and beyond that has a larger societal responsibility, as citizen and as health expert, to be involved in establishing humane allocation policies at both the institutional and societal levels (Junkerman and Schiedermyer, 53-4).