CHAPTER

2

Moral and Ethical Issues

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OUTLINE

AFTER COMPLETING THIS CHAPTER, STUDENTS WILL BE ABLE TO:

- Define and distinguish between the terms *morals* and *ethics*.
- Present the rationale underlying two major philosophical schools of thought: *utilitarianism* and *nonconsequentialism*.
- Present the codes of ethics for the medical profession, nursing profession, and biomedical engineering.
- Identify the modern moral dilemmas, including redefining death, deciding how

to care for the terminally ill, and human experimentation, which arise from the two moral norms: *beneficence* (the provision of benefits) and *nonmaleficence* (the avoidance of harm).

- Discuss the moral judgments associated with present policies regarding the regulation of the development and use of new medical devices.

The tremendous infusion of technology into the practice of medicine has created a new medical era. Advances in material science have led to the production of artificial limbs, heart valves, and blood vessels, thereby permitting "spare parts" surgery. Numerous patient disorders are now routinely diagnosed using a wide range of highly sophisticated imaging devices, and the lives of many patients are being extended through significant improvements in resuscitative and supportive devices, such as respirators, pacemakers, and artificial kidneys.

These technological advances, however, have not been benign. They have had significant moral consequences. Provided with the ability to develop cardiovascular assist devices, perform organ transplants, and maintain the breathing and heartbeat of terminally ill patients, society has been forced to reexamine the meaning of such terms as *death, quality of life, heroic efforts,* and *acts of mercy*, and to consider such moral issues as the right of patients to refuse treatment (living wills) and to participate in experiments (informed consent). As a result, these technological advances have made the moral dimensions of health care more complex and have posed new and troubling moral dilemmas for medical professionals, the biomedical engineer, and society at large.

The purpose of this chapter is to examine some of the moral questions related to the use of new medical technologies. The objective, however, is not to provide solutions or recommendations for these questions. Rather, the intent is to demonstrate that each technological advance has consequences that affect the very core of human values.

Technology and ethics are not foreigners; they are neighbors in the world of human accomplishment. Technology is a human achievement of extraordinary ingenuity and utility and is quite distant from the human accomplishment of ethical values. They face each other rather than interface. The personal face of ethics looks at the impersonal face of technology in order to comprehend technology's potential and its limits. The face of technology looks to ethics to be directed to human purposes and benefits.

In the process of making technology and ethics face each other, it is our hope that individuals engaged in the development of new medical devices, as well as those responsible for the care of patients, will be stimulated to examine and evaluate critically "accepted" views and to reach their own conclusions. This chapter, therefore, begins with some definitions related to morality and ethics, followed by a more detailed discussion of some of the moral issues of special importance to biomedical engineers.

2.1 MORALITY AND ETHICS: A DEFINITION OF TERMS

From the very beginning, individuals have raised concerns about the nature of life and its significance. Many of these concerns have been incorporated into the four fundamental questions posed by the German philosopher Immanuel Kant (1724–1804): *What can I know?*

What ought I to do? What can I hope? What is man? Evidence that early societies raised these questions can be found in the generation of rather complex codes of conduct embedded in the customs of the earliest human social organization: the tribe. By 600 BC, the Greeks were successful in reducing many primitive speculations, attitudes, and views on these questions to some type of order or system and integrating them into the general body of wisdom called *philosophy*. Being seafarers and colonizers, the Greeks had close contact with many different peoples and cultures. In the process, struck by the variety of customs, laws, and institutions that prevailed in the societies that surrounded them, they began to examine and compare all human conduct in these societies. This part of philosophy they called *ethics.*

The term *ethics* comes from the Greek *ethos,* meaning "custom." On the other hand, the Latin word for custom is *mos,* and its plural, *mores,* is the equivalent of the Greek *ethos* and the root of the words *moral* and *morality.* Although both terms (*ethics* and *morality*) are often used interchangeably, there is a distinction between them that should be made.

Philosophers define ethics as a particular kind of study and use morality to refer to its subject matter. For example, customs that result from some abiding principal human interaction are called *morals.* Some examples of morals in our present society are telling the truth, paying one's debts, honoring one's parents, and respecting the rights and property of others. Most members of society usually consider such conduct not only customary but also correct or right. Thus, morality encompasses what people believe to be right and good and the reasons they give for it.

Most of us follow these rules of conduct and adjust our lifestyles in accordance with the principles they represent. Many even sacrifice life itself rather than diverge from them, applying them not only to their own conduct but also to the behavior of others. Individuals who disregard these accepted codes of conduct are considered deviants and, in many cases, are punished for engaging in an activity that society as a whole considers unacceptable. For example, individuals committing "criminal acts" (defined by society) are often "outlawed" and, in many cases, severely punished. These judgments regarding codes of conduct, however, are not inflexible; they must continually be modified to fit changing conditions and thereby avoid the trauma of revolution as the vehicle for change.

While morality represents the codes of conduct of a society, ethics is the study of right and wrong, of good and evil in human conduct. Ethics is not concerned with providing any judgments or specific rules for human behavior, but rather with providing an objective analysis about what individuals "ought to do." Defined in this way, it represents the philosophical view of morals, and, therefore, is often referred to as *moral philosophy.*

Consider the following three questions: "Should badly deformed infants be kept alive?"; "Should treatment be stopped to allow a terminally ill patient to die?"; "Should humans be used in experiments?" Are these questions of morality or ethics? In terms of the definitions just provided, all three of these inquiries are questions of moral judgment.

Philosophers argue that all moral judgments are considered to be "normative judgments"—that is, they can be recognized simply by their characteristic evaluative terms such as good, bad, right, wrong, and so on. Typical normative judgments include the following:

- Stealing is wrong.
- Everyone ought to have access to an education.
- Voluntary euthanasia should not be legalized.

Each of these judgments expresses an evaluation; that is, it conveys a negative or positive attitude toward some state of affairs. Each, therefore, is intended to play an action-guiding function.

Arriving at moral judgments, however, requires knowledge of valid moral standards in our society. Nevertheless, how is such knowledge obtained? The efforts to answer this question lie in two competing schools of thought that currently dominate normative ethical theory: *utilitarianism,* a form of consequentialism, and *Kantianism,* a form of nonconsequentialism. Consequentialism holds that the morally right action is always the one among the available options that has the best consequences. An important implication of consequentialism is that no specific actions or courses of conduct are automatically ruled out as immoral or ruled in as morally obligatory. The rightness or wrongness of an action is wholly contingent upon its effects.

According to utilitarianism, there are two steps to determining what ought to be done in any situation. First, determine which courses of action are open. Second, determine the consequences of each alternative. When this has been accomplished, the morally right course of action is the one that maximizes pleasure, minimizes pain, or both—the one that does the "greatest good for the greatest number." Because the central motivation driving the design, development, and use of medical devices is improvement of medicine's capacity to protect and restore health, an obvious virtue of utilitarianism is that it assesses medical technology in terms of what many believe makes health valuable: the attainment of well-being and the avoidance of pain.

Utilitarianism, therefore, advocates that the end justifies the means. As long as any form of treatment maximizes good consequences, it should be used. Many people, though, believe that the end does not always justify the means and that individuals have rights that are not to be violated no matter how good the consequences might be.

In opposition to utilitarianism stands the school of normative ethical thought known as *nonconsequentialism*. Proponents of this school deny that moral evaluation is simply and wholly a matter of determining the consequences of human conduct. They agree that other considerations are relevant to moral assessment and so reject the view that morally right conduct is whatever has the best consequences. Based largely on the views of Immanuel Kant, this ethical school of thought insists that there is something uniquely precious about human beings from the moral point of view. According to Kant's theory, humans have certain "rights" that do not apply to any other animal. For example, the moral judgments that we should not kill and eat one another for food or hunt one another for sport or experiment on one another for medical science are all based on this view of human rights. Humans are, in short, owed a special kind of respect simply because they are people.

These two philosophies may be extended to apply to animal testing in scientific research as well. On the utilitarianism side of the argument for animal experimentation, the health care advancements for humans made possible through animal research far outweigh the majority of arguments against the practice. In contrast, nonconsequentialism would state that maltreatment of innocent and unprotected living beings is morally unjust and as such is an inappropriate means to the ends of better health care for people. Ultimately researchers must decide for themselves, based on their own beliefs and reasoning, which philosophy wins out.

In terms of human experimentation, to better understand the Kantian perspective, it may be helpful to recognize that Kant's views are an attempt to capture in secular form a basic

tenet of Christian morality. What makes human beings morally special entities deserving a unique type of respect? Christianity answers in terms of the doctrine of ensoulment. This doctrine holds that only human beings are divinely endowed with an eternal soul. According to Christian ethics, the soul makes humans the only beings with intrinsic value. Kant's secular version of the doctrine of ensoulment asserts that human beings are morally unique and deserve special respect because of their autonomy. Autonomy is taken by Kant to be the capacity to make choices based on rational deliberation. The central task of ethics then is to specify what human conduct is required to respect the unique dignity of human beings. For most Kantians, this means determining what limits human beings must observe in the way they treat one another, and this, in turn, is taken to be a matter of specifying each individual's fundamental moral rights.

These two ethical schools of thought, therefore, provide some rationale for moral judgments. However, when there is no clear moral judgment, one is faced with a dilemma. In medicine, moral dilemmas arise in those situations that raise fundamental questions about right and wrong in the treatment of sickness and the promotion of health in patients. In many of these situations, the health professional usually faces two alternative choices, neither of which seems to be a satisfactory solution to the problem. For example, is it more important to preserve life or to prevent pain? Is it right to withhold treatment when doing so may lead to a shortening of life? Does an individual have the right to refuse treatment when refusing it may lead to death? All these situations seem to have no clear-cut imperative based on our present set of convictions about right and wrong. That is the dilemma raised by Kant: *What ought I do?*

CASE STUDY: STEM CELL RESEARCH

At the moment of conception—that is, when a sperm penetrates an egg—the process of fertilization occurs. The formation of an embryo is initiated. Once the sperm enters the egg, there is an immediate opening of ion channels, which depolarizes the plasma membrane of the cell and prevents other sperm from fusing with it. DNA replication then begins, and the first cell division occurs approximately 36 hours later. As the process continues, the cell begins to experience cleavage, where the cells repeatedly divide, cycling between the S (DNA synthesis) and M (mitosis) phases of cell division, essentially skipping the G_1 and G_2 phases, when most cell growth normally occurs. Thus, there is no net growth of the cells, merely subdivision into smaller cells, individually called blastomeres.

Five days after fertilization, the number of cells composing the embryo is in the hundreds, and the cells form tight junctions characteristic of a compact epithelium, which is arranged around a central cavity. This is the embryonic stage known as the blastocyst. Within the cavity exists a mass of cells, which protrude inward. These cells are known as the inner cell mass and become the embryo. The exterior cells are the trophoblast and eventually form the placenta. It is the cells from the inner cell mass of the blastocyst, however, that, when isolated and grown in a culture, are identified as embryonic stem cells.

It is important to note that if cell division continues, determination and differentiation happen. Differentiation occurs when a cell begins to exhibit the specific attributes of a predestined specialized cellular role. Determination is related to differentiation but is somewhat dissimilar.

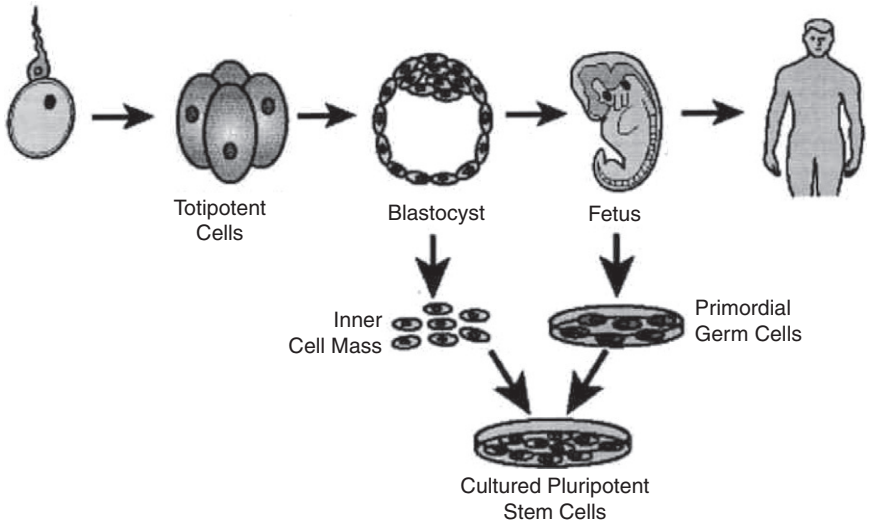

FIGURE 2.1 Using the inner cell mass to form pluripotent stem cells. *Courtesy of http://www.nih.gov/news/stemcell/primer.htm.*

When a cell group that has been determined is transplanted, it will not assimilate with the other cells but will grow into cells that comprised the original organ it was destined to become.

Since the process of obtaining embryonic stem cells (Figure 2.1) destroys the embryo, the following questions arise:

1. Is the embryo a living human being, entitled to all of the same rights that a human at any other age would be granted? Discuss the answer to this question from a Utilitarian and Kantian point of view.
2. Should any research that is potentially beneficial to the well-being of mankind be pursued? In 2009, President Obama passed groundbreaking legislation entitled "Executive Order 13505—Removing Barriers to Responsible Scientific Research Involving Human Stem Cells." The order calls for a review of NIH (National Institute of Health) guidelines for stem cell research and, more importantly, removes the requirement of President Action to approve NIH-funded stem cell investigations.
3. Should the federal government support (i.e., use tax dollars to fund) such research? Or, in contrast, should the government be allowed to interfere?

In the practice of medicine, moral dilemmas are certainly not new. They have been present throughout medical history. As a result, over the years there have been efforts to provide a set of guidelines for those responsible for patient care. These efforts have resulted in the development of specific codes of professional conduct. Let us examine some of these codes or guidelines.

For the medical profession, the World Medical Association adopted a version of the Hippocratic Oath entitled the *Geneva Convention Code of Medical Ethics* in 1949. This declaration contains the following statements:

I solemnly pledge myself to consecrate my life to the services of humanity;
I will give to my teachers the respect and gratitude which is their due;
I will practice my profession with conscience and dignity;
The health of my patient will be my first consideration;
I will respect the secrets which are confided in me;
I will maintain by all the means in my power, the honour and the noble traditions of the medical profession;
My colleagues will be my brothers;
I will not permit considerations of religion, nationality, race, party politics, or social standing to intervene between my duty and my patient;
I will maintain the utmost respect for human life from the time of conception, even under threat;
I will not use my medical knowledge contrary to the laws of humanity;
I make these promises solemnly, freely, and upon my honour.

In the United States, the American Medical Association (AMA) adopted a set of Principles of Medical Ethics in 1980 and revised them in June 2001. A comparison of the two sets of principles is provided following.

Revised Principles
Version adopted by the AMA House of Delegates, June 17, 2001

The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. As a member of this profession, a physician must recognize responsibility to patients first and foremost, as well as to society, to other health professionals, and to self. The following Principles adopted by the American Medical Association are not laws but standards of conduct that define the essentials of honorable behavior for the physician.

I. A physician shall be dedicated to providing competent medical care, with compassion and respect for human dignity and rights.
II. A physician shall uphold the standards of professionalism, be honest in all professional interactions, and strive to report physicians deficient in character or

Previous Principles
As adopted by the AMA's House of Delegates, 1980

The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient. As a member of this profession, a physician must recognize responsibility not only to patients, but also to society, to other health professionals, and to self. The following Principles adopted by the American Medical Association are not laws but standards of conduct that define the essentials of honorable behavior for the physician.

I. A physician shall be dedicated to providing competent medical service with compassion and respect for human dignity.
II. A physician shall deal honestly with patients and colleagues, and strive to expose those physicians deficient in character or competence, or who engage in fraud or deception.

competence, or engaging in fraud or deception, to appropriate entities.	
III. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.	III. A physician shall respect the law and also recognize a responsibility to seek changes in those requirements which are contrary to the best interests of the patient.
IV. A physician shall respect the rights of patients, colleagues, and other health professionals, and shall safeguard patient confidences within the constraints of the law.	IV. A physician shall respect the rights of patients, of colleagues, and of other health professionals, and shall safeguard patient confidences within the constraints of the law.
V. A physician shall continue to study, apply, and advance scientific knowledge; make relevant information available to patients, colleagues, and the public; obtain consultation; and use the talents of other health professionals when indicated.	V. A physician shall continue to study, apply and advance scientific knowledge; make relevant information available to patients, colleagues, and the public; obtain consultation; and use the talents of other health professionals when indicated.
VI. A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical care.	VI. A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical services.
VII. A physician shall recognize a responsibility to participate in activities contributing to the improvement of the community and the betterment of public health.	VII. A physician shall recognize a responsibility to participate in activities contributing to an improved community.
VIII. A physician shall, while caring for a patient, regard responsibility to the patient as paramount.	
IX. A physician shall support access to medical care for all people.	

For the nursing profession, the American Nurses Association formally adopted in 1976 the *Code For Nurses,* whose statements and interpretations provide guidance for conduct and relationships in carrying out nursing responsibilities:

PREAMBLE: The *Code for Nurses* is based on belief about the nature of individuals, nursing, health, and society. Recipients and providers of nursing services are viewed as individuals and groups who possess basic rights and responsibilities, and whose values and circumstances

command respect at all times. Nursing encompasses the promotion and restoration of health, the prevention of illness, and the alleviation of suffering. The statements of the Code and their interpretation provide guidance for conduct and relationships in carrying out nursing responsibilities consistent with the ethical obligations of the profession and quality in nursing care.

> *The nurse provides services with respect for human dignity and the uniqueness of the client, unrestricted by considerations of social or economic status, personal attributes, or the nature of health problems.*
> *The nurse safeguards the client's right to privacy by judiciously protecting information of a confidential nature.*
> *The nurse acts to safeguard the client and the public when health care and safety are affected by the incompetent, unethical, or illegal practice of any person.*
> *The nurse assumes responsibility and accountability for individual nursing judgments and actions.*
> *The nurse maintains competence in nursing.*
> *The nurse exercises informed judgment and uses individual competence and qualifications as criteria in seeking consultation, accepting responsibilities, and delegating nursing activities to others.*
> *The nurse participates in activities that contribute to the ongoing development of the profession's body of knowledge.*
> *The nurse participates in the profession's efforts to implement and improve standards of nursing.*
> *The nurse participates in the profession's efforts to establish and maintain conditions of employment conducive to high-quality nursing care.*
> *The nurse participates in the profession's effort to protect the public from misinformation and misrepresentation and to maintain the integrity of nursing.*
> *The nurse collaborates with members of the health professions and other citizens in promoting community and national efforts to meet the health needs of the public.*

These codes take as their guiding principle the concepts of service to humankind and respect for human life. When reading these codes of conduct, it is difficult to imagine that anyone could improve on them as summary statements of the primary goals of individuals responsible for the care of patients. However, some believe that such codes fail to provide answers to many of the difficult moral dilemmas confronting health professionals today. For example, in many situations, all the fundamental responsibilities of the nurse cannot be met at the same time. When a patient suffering from a massive insult to the brain is kept alive by artificial means and this equipment is needed elsewhere, it is not clear from these guidelines how "nursing competence is to be maintained to conserve life and promote health." Although it may be argued that the decision to treat or not to treat is a medical and not a nursing decision, both professions are so intimately involved in the care of patients that they are both concerned with the ultimate implications of any such decision.

For biomedical engineers, an increased awareness of the ethical significance of their professional activities has also resulted in the development of codes of professional ethics. Typically consisting of a short list of general rules, these codes express both the minimal standards to which all members of a profession are expected to conform and the ideals for which all members are expected to strive. Such codes provide a practical guide for the ethical conduct of the profession's practitioners. Consider, for example, the code of ethics endorsed by the American College of Clinical Engineers:

As a member of the American College of Clinical Engineering, I subscribe to the established Code of Ethics in that I will:

- *Accurately represent my level of responsibility, authority, experience, knowledge, and education.*
- *Strive to prevent a person from being placed at risk due to the use of technology.*
- *Reveal conflicts of interest that may affect information provided or received.*
- *Respect the confidentiality of information.*
- *Work toward improving the delivery of health care.*
- *Work toward the containment of costs by the better management and utilization of technology.*
- *Promote the profession of clinical engineering.*

Although these codes can be useful in promoting ethical conduct, such rules obviously cannot provide ethical guidance in every situation. A profession that aims to maximize the ethical conduct of its members must not limit the ethical consciousness of its members to knowledge of their professional code alone. It must also provide them with resources that will enable them to determine what the code requires in a particular concrete situation and thereby enable them to arrive at ethically sound judgments in situations in which the directives of the code are ambiguous or simply do not apply.

2.2 TWO MORAL NORMS: BENEFICENCE AND NONMALEFICENCE

Two moral norms have remained relatively constant across the various moral codes and oaths that have been formulated for health care providers since the beginnings of Western medicine in classical Greek civilization. They are *beneficence,* which is the provision of benefits, and *nonmaleficence,* which is the avoidance of doing harm. These norms are traced back to a body of writings from classical antiquity known as the *Hippocratic Corpus.* Although these writings are associated with the name of Hippocrates, the acknowledged founder of Western medicine, medical historians remain uncertain whether any of them, including the *Hippocratic Oath,* were actually his work. Although portions of the *Corpus* are believed to have been authored during the sixth century BC, other portions are believed to have been written as late as the beginning of the Christian era. Medical historians agree that many of the specific moral directives of the *Corpus* represent neither the actual practices nor the moral ideals of the majority of physicians of Ancient Greece and Rome.

Nonetheless, the general injunction *"As to disease, make a habit of two things: (1) to help or, (2) at least, to do no harm"* was accepted as a fundamental medical ethical norm by at least some ancient physicians. With the decline of Hellenistic civilization and the rise of Christianity, beneficence and nonmaleficence became increasingly accepted as the fundamental principles of morally sound medical practice. Although beneficence and nonmaleficence were regarded merely as concomitant to the craft of medicine in classical Greece and Rome, the emphasis upon compassion and the brotherhood of humankind, central to Christianity, increasingly made these norms the only acceptable motives for medical practice. Even today, the provision of benefits and the avoidance of doing harm are stressed just as much in virtually all contemporary Western codes of conduct for health professionals as they were in the oaths and codes that guided the health-care providers of past centuries.

Traditionally, the ethics of medical care has given greater prominence to nonmaleficence than to beneficence. This priority was grounded in the fact that, historically, medicine's capacity to do harm far exceeded its capacity to protect and restore health. Providers of health care possessed many treatments that posed clear and genuine risks to patients and that offered little prospect of benefit. Truly effective therapies were all too rare. In this context, it is surely rational to give substantially higher priority to avoiding harm than to providing benefits.

The advent of modern science changed matters dramatically. Knowledge acquired in laboratories, tested in clinics, and verified by statistical methods has increasingly dictated the practice of medicine. This ongoing alliance between medicine and science became a critical source of the plethora of technologies that now pervade medical care. The impressive increases in therapeutic, preventive, and rehabilitative capabilities that these technologies have provided have pushed beneficence to the forefront of medical morality. Some have even gone so far as to hold that the old medical ethic of *"Above all, do no harm"* should be superseded by the new ethic *"The patient deserves the best."* However, the rapid advances in medical technology capabilities have also produced great uncertainty as to what is most beneficial or least harmful for the patient. In other words, along with increases in ability to be beneficent, medicine's technology has generated much debate about what actually counts as beneficent or nonmaleficent treatment. Having reviewed some of the fundamental concepts of ethics and morality, let us now turn to several specific moral issues posed by the use of medical technology.

2.3 REDEFINING DEATH

Although medicine has long been involved in the observation and certification of death, many of its practitioners have not always expressed philosophical concerns regarding the beginning of life and the onset of death. Since medicine is a clinical and empirical science, it would seem that health professionals had no medical need to consider the concept of death: the fact of death was sufficient. The distinction between life and death was viewed as the comparison of two extreme conditions separated by an infinite chasm. With the advent of technological advances in medicine to assist health professionals to prolong life, this view has changed.

There is no doubt that the use of medical technology has in many instances warded off the coming of the grim reaper. One need only look at the trends in average life expectancy for confirmation. For example, in the United States today, the average life expectancy for males is 74.3 years and for females 76 years, whereas in 1900 the average life expectancy for both sexes was only 47 years. Infant mortality has been significantly reduced in developed nations where technology is an integral part of the culture. Premature births no longer constitute a threat to life because of the artificial environment that medical technology can provide. Today, technology has not only helped individuals avoid early death but has also been effective in delaying the inevitable. Pacemakers, artificial kidneys, and a variety of other medical devices have enabled individuals to add many more productive years to their lives. Technology has been so successful that health professionals responsible for the care of critically ill patients have been able to maintain their "vital signs of life" for extensive periods of time. In the process, however, serious philosophical questions concerning the quality of the life provided these patients have arisen.

Consider the case of the patient who sustains a serious head injury in an automobile accident. To the attendants in the ambulance who reached the scene of the accident, the patient was unconscious but still alive with a beating heart. After the victim was rushed to the hospital and into the emergency room, the resident in charge verified the stability of the vital signs of heartbeat and respiration during examination and ordered a computerized tomography (CT) scan to indicate the extent of the head injury. The results of this procedure clearly showed extensive brain damage. When the EEG was obtained from the scalp electrodes placed about the head, it was noted to be significantly abnormal. In this situation, then, the obvious questions arise: What is the status of the patient? Is the patient alive?

Alternatively, consider the events encountered during one open-heart surgery. During this procedure, the patient was placed on the heart bypass machine while the surgeon attempted to correct a malfunctioning valve. As the complex and long operation continued, the EEG monitors that had indicated a normal pattern of electrical activity at the onset of the operation suddenly displayed a relatively straight line indicative of feeble electrical activity. However, since the heart-lung bypass was maintaining the patient's so-called vital signs, what should the surgeon do? Should the medical staff continue on the basis that the patient is alive, or is the patient dead?

The increasing occurrence of these situations has stimulated health professionals to reexamine the definition of "death." In essence, advances in medical technology that delay death actually hastened its redefinition. This should not be so surprising because the definition of death has always been closely related to the extent of medical knowledge and available technology. For many centuries, death was defined solely as the absence of breathing. Since it was felt that the spirit of the human being resided in the spiritus (breath), its absence became indicative of death. With the continuing proliferation of scientific information regarding human physiology and the development of techniques to revive a nonbreathing person, attention turned to the pulsating heart as the focal point in determination of death. However, this view was to change through additional medical and technological advances in supportive therapy, resuscitation, cardiovascular assist devices, and organ transplantation.

As understanding of the human organism increased, it became obvious that one of the primary constituents of the blood is oxygen and that any organ deprived of oxygen for a specified period of time will cease to function and die. The higher functions of the brain are particularly vulnerable to this type of insult, since the removal of oxygen from the blood supply even for a short period of time (three minutes) produces irreversible damage to the brain tissues. Consequently, the evidence of "death" began to shift from the pulsating heart to the vital, functioning brain. Once medicine was provided with the means to monitor the brain's activity (i.e., the EEG), another factor was introduced in the definition of death. Advocates of the concept of brain death argued that the human brain is truly essential to life. When the brain is irreversibly damaged, so are the functions that are identified with self and our own humanness: memory, feeling, thinking, knowledge, and so on.

As a result, it became widely accepted that the meaning of clinical death implies that the spontaneous activity of the lungs, heart, and brain is no longer present. The irreversible cessation of functioning of all three major organs—the heart, lungs, and brain—was required before anyone was pronounced dead. Although damage to any other organ system such as the liver or kidney may ultimately cause the death of the individual through a fatal effect on the essential functions of the heart, lungs, or brain, this aspect was not included in the definition of clinical death.

With the development of modern respirators, however, the medical profession encountered an increasing number of situations in which a patient with irreversible brain damage could be maintained almost indefinitely. Once again, a new technological advance created the need to reexamine the definition of death.

The movement toward redefining death received considerable impetus with the publication of a report sponsored by the Ad Hoc Committee of the Harvard Medical School in 1968, in which the committee offered an alternative definition of death based on the functioning of the brain. The report of this committee was considered a landmark attempt to deal with death in light of technology.

In summary, the criteria for death established by this committee included the following: (1) the patient must be unreceptive and unresponsive—that is, in a state of irreversible coma; (2) the patient must have no movements of breathing when the mechanical respirator is turned off; (3) the patient must not demonstrate any reflexes; and (4) the patient must have a flat EEG for at least 24 hours, indicating no electrical brain activity. When these criteria are satisfied, then death may be declared.

At the time, the committee also strongly recommended that the decision to declare the person dead and then to turn off the respirator should not be made by physicians involved in any later efforts to transplant organs or tissues from the deceased individual. In this way, a prospective donor's death would not be hastened merely for the purpose of transplantation. Thus, complete separation of authority and responsibility for the care of the recipient from the physician or group of physicians who are responsible for the care of the prospective donor is essential.

The shift to a brain-oriented concept involved deciding that much more than just biological life is necessary to be a human person. The brain death concept was essentially a statement that mere vegetative human life is not personal human life. In other words, an otherwise intact and alive but brain-dead person is not a human person. Many of us have taken for granted the assertion that being truly alive in this world requires an "intact functioning brain." Yet, precisely this issue was at stake in the gradual movement from using heartbeat and respiration as indices of life to using brain-oriented indices instead.

Indeed, total and irreparable loss of brain function, referred to as "brainstem death," "whole brain death," or, simply, "brain death," has been widely accepted as the legal standard for death. By this standard, an individual in a state of brain death is legally indistinguishable from a corpse and may be legally treated as one even though respiratory and circulatory functions may be sustained through the intervention of technology. Many take this legal standard to be the morally appropriate one, noting that once destruction of the brainstem has occurred, the brain cannot function at all, and the body's regulatory mechanisms will fail unless artificially sustained. Thus mechanical sustenance of an individual in a state of brain death is merely postponement of the inevitable and sustains nothing of the personality, character, or consciousness of the individual. It is simply the mechanical intervention that differentiates such an individual from a corpse, and a mechanically ventilated corpse is a corpse nonetheless.

Even with a consensus that brainstem death is death, and thus that an individual in such a state is indeed a corpse, difficult cases remain. Consider the case of an individual in a persistent vegetative state, the condition known as "neocortical death." Although severe brain injury has been suffered, enough brain function remains to make mechanical sustenance of respiration and circulation unnecessary. In a persistent vegetative state, an individual exhibits no purposeful response to external stimuli and no evidence of self-awareness. The eyes

may open periodically, and the individual may exhibit sleep-wake cycles. Some patients even yawn, make chewing motions, or swallow spontaneously. Unlike the complete unresponsiveness of individuals in a state of brainstem death, a variety of simple and complex responses can be elicited from an individual in a persistent vegetative state. Nonetheless, the chances that such an individual will regain consciousness are remote. Artificial feeding, kidney dialysis, and the like make it possible to sustain an individual in a state of neocortical death for decades.

If brainstem death is death, is neocortical death also death? Again, the issue is not a straightforward factual matter. For it, too, is a matter of specifying which features of living individuals distinguish them from corpses and so make treatment of them as corpses morally impermissible. Irreparable cessation of respiration and circulation, the classical criterion for death, would entail that an individual in a persistent vegetative state is not a corpse and so, morally speaking, must not be treated as one. The brainstem death criterion for death would also entail that a person in a state of neocortical death is not yet a corpse. On this criterion, what is crucial is that brain damage be severe enough to cause failure of the regulatory mechanisms of the body.

Is an individual in a state of neocortical death any less in possession of the characteristics that distinguish the living from cadavers than one whose respiration and circulation are mechanically maintained? It is a matter that society must decide. And until society decides, it is not clear what counts as beneficent or nonmaleficent treatment of an individual in a state of neocortical death.

CASE STUDY: TERRI SCHIAVO AND THE BRAIN DEATH DEBATE

In February 1990, an otherwise healthy 27-year-old Terri Schiavo suffered heart failure in her home and fell into a coma. While Schiavo ultimately woke and initially proved responsive, after a year of multiple rehabilitation facilities and nursing homes, the by then 28-year-old was diagnosed as in an irreversible persistent vegetative state (PVS). In 1998, Schiavo's husband, Michael Schiavo, made a petition to the Florida courts to remove his wife from life support, a petition fought vehemently by the woman's parents.

In 2001, after a doctor confirmed brain death with a report of significant brainstem damage and 80 percent loss of upper brain function, Schiavo's feeding tube was removed, but was replaced days later, following a Court Appeal by her parents. Ultimately, the feeding tube was ordered to be removed on three separate occasions, each time her legal guardian and husband fighting to allow his wife to "die in peace," while her parents insisted that their daughter maintained cognitive function and requested more tests.

Finally in 2005, 15 years after her injury, and under constant national media coverage, Schiavo died from dehydration two weeks after her tube had been removed for the final time and while her case was still pending with the highest word in the nation: the Supreme Court.

1. Without a Living Will, who is responsible for deciding the would-be intentions of a victim of brain death? Who is responsible for mediation when loved ones disagree?
2. Who is responsible for the years of health care costs of a potentially brain dead individual? In 2006, Rom Houben, a man presumed brain dead for 23 years, was discovered to have full brain function after a series of advanced brain scan imaging tests. Houben was paralyzed in an accident

in 1983 at the age of 20. A formal martial arts enthusiast, Houben was assumed to be in a PVS for over two decades. After therapy he is now able to communicate via typing, and he reads books while lying down, using an assistive device. "I want to read," says Houben, via keyboard, "talk with my friends via the computer, and enjoy my life now that people know I am not dead."

3. With diagnosis technologies constantly in development, should PVS victims ever be "allowed to die"?

2.4 THE TERMINALLY ILL PATIENT AND EUTHANASIA

Terminally ill patients today often find themselves in a strange world of institutions and technology devoted to assisting them in their fight against death. However, at the same time, this modern technologically oriented medical system may cause patients and their families considerable economic, psychological, and physical pain. In enabling medical science to prolong life, modern technology has in many cases made dying slower and more undignified. As a result of this situation, there is a moral dilemma in medicine. Is it right or wrong for medical professionals to stop treatment or administer a lethal dose to terminally ill patients?

This problem has become a major issue for our society to consider. Although death is all around us in the form of accidents, drug overdoses, alcoholism, murders, and suicides, for most of us, the end lies in growing older and succumbing to some form of chronic illness. As the aged approach the end of life's journey, they may eventually wish for the day when all troubles can be brought to an end. Such a desire, frequently shared by a compassionate family, is often shattered by therapies provided with only one concern: to prolong life regardless of the situation. As a result, many claim a dignified death is often not compatible with today's standard medical view.

Consider the following hypothetical version of the kind of case that often confronts contemporary patients, their families, health care workers, and society as a whole. Suppose a middle-aged man suffers a brain hemorrhage and loses consciousness as a result of a ruptured aneurysm. Suppose that he never regains consciousness and is hospitalized in a state of neocortical death, a chronic vegetative state. His life is maintained by a surgically implanted gastronomy tube that drips liquid nourishment from a plastic bag directly into his stomach. The care of this individual takes seven and one-half hours of nursing time daily and includes shaving, oral hygiene, grooming, attending to his bowels and bladder, and so forth. Suppose further that his wife undertakes legal action to force his caregivers to end all medical treatment, including nutrition and hydration so complete bodily death of her husband will occur. She presents a preponderance of evidence to the court to show that her husband would have wanted just this result in these circumstances.

The central moral issue raised by this sort of case is whether the quality of the individual's life is sufficiently compromised to make intentional termination of that life morally permissible. While alive, he made it clear to both family and friends that he would prefer to be allowed to die rather than be mechanically maintained in a condition of irretrievable loss of consciousness. Deciding whether his judgment in such a case should be allowed requires deciding which capacities and qualities make life worth living, which qualities are sufficient to endow it with value worth sustaining, and whether their absence justifies deliberate termination of a life, at least when this would be the wish of the individual in question. Without this decision, the traditional norms of medical ethics, beneficence and

nonmaleficence, provide no guidance. Without this decision, it cannot be determined whether termination of life support is a benefit or harm to the patient.

For many individuals, the fight for life is a correct professional view. They believe that the forces of medicine should always be committed to using innovative ways of prolonging life for the individual. However, this cannot be the only approach to caring for the terminally ill. Certain moral questions regarding the extent to which physicians engaged in heroic efforts to prolong life must be addressed if the individual's rights are to be preserved. The goal of those responsible for patient care should not solely be to prolong life as long as possible by the extensive use of drugs, operations, respirators, hemodialyzers, pacemakers, and the like, but rather to provide a reasonable "quality of life" for each patient. It is out of this new concern that euthanasia has once again become a controversial issue in the practice of medicine.

The term *euthanasia* is derived from two Greek words meaning "good" and "death." Euthanasia was practiced in many primitive societies in varying degrees. For example, on the island of Cos, the ancient Greeks assembled elderly and sick people at an annual banquet to consume a poisonous potion. Even Aristotle advocated euthanasia for gravely deformed children. Other cultures acted in a similar manner toward their aged by abandoning them when they felt these individuals no longer served any useful purpose. However, with the spread of Christianity in the Western world, a new attitude developed toward euthanasia. Because of the Judeo-Christian belief in the biblical statements "Thou shalt not kill" (Exodus 20: 13) and "He who kills a man should be put to death" (Leviticus 24: 17), the practice of euthanasia decreased. As a result of these moral judgments, killing was considered a sin, and the decision about whether someone should live or die was viewed solely as God's responsibility, not humans'.

In today's society, euthanasia implies to many "death with dignity," a practice to be followed when life is merely being prolonged by machines and no longer seems to have value. In many instances, it has come to mean a contract for the termination of life in order to avoid unnecessary suffering at the end of a fatal illness and, therefore, has the connotation of relief from pain.

Discussions of the morality of euthanasia often distinguish active from passive euthanasia, a distinction that rests upon the difference between an act of commission and an act of omission. When failure to take steps that could effectively forestall death results in an individual's demise, the resultant death is an act of omission and a case of letting a person die. When a death is the result of doing something to hasten the end of a person's life (for example, giving a lethal injection), that death is caused by an act of commission and is a case of killing a person. The important difference between active and passive euthanasia is that in passive euthanasia, the physician does not do anything to bring about the patient's death. The physician does nothing, and death results due to whatever illness already afflicts the patient. In active euthanasia, however, the physician does something to bring about the patient's death. The physician who gives the patient with cancer a lethal injection has caused the patient's death, whereas if the physician merely ceases treatment, the cancer is the cause of death.

In active euthanasia, someone must do something to bring about the patient's death, and in passive euthanasia, the patient's death is caused by illness rather than by anyone's conduct. Is this notion correct? Suppose a physician deliberately decides not to treat a patient who is terminally ill, and the patient dies. Suppose further that the physician were to attempt to exonerate himself by saying, "I did nothing. The patient's death was the result

of illness. I was not the cause of death." Under current legal and moral norms, such a response would have no credibility. The physician would be blameworthy for the patient's death as surely as if he or she had actively killed the patient. Thus, the actions taken by a physician to continue treatment to the very end are understood.

Euthanasia may also be classified as *involuntary* or *voluntary*. An act of euthanasia is involuntary if it hastens the individual's death for his or her own good, but against their wishes. Involuntary euthanasia, therefore, is no different in any morally relevant way from unjustifiable homicide. However, what happens when the individual is incapable of agreeing or disagreeing? Suppose that a terminally ill person is unconscious and cannot make his or her wishes known. Would hastening their death be permissible? It would be if there was substantial evidence that the individual has given prior consent. The individual may have told friends and relatives that, under certain circumstances, efforts to prolong their life should not be undertaken or continued and might even have recorded their wishes in the form of a living will or an audio- or videotape. When this level of substantial evidence of prior consent exists, the decision to hasten death would be morally justified. A case of this sort would be a case of voluntary euthanasia.

For a living will to be valid, the person signing it must be of sound mind at the time the will is made and shown not to have altered their opinion in the interim between its signing and the onset of the illness. In addition, the witnesses must not be able to benefit from the individual's death. As the living will itself states, it is not a legally binding document. It is essentially a passive request and depends on moral persuasion. Proponents of the will, however, believe that it is valuable in relieving the burden of guilt often carried by health professionals and the family in making the decision to allow a patient to die.

Those who favor euthanasia point out the importance of individual rights and freedom of choice and look on euthanasia as a kindness ending the misery endured by the patient. The thought of a dignified death is much more attractive than the process of continuous suffering and gradual decay into nothingness. Viewing each person as a rational being possessing a unique mind and personality, proponents argue that terminally ill patients should have the right to control the ending of their own life.

On the other hand, those opposed to euthanasia demand to know who has the right to end the life of another. Some use religious arguments, emphasizing that euthanasia is in direct conflict with the belief that only God has the power to decide when a human life ends. Their view is that anyone who practices euthanasia is essentially acting in the place of God and that no human should ever be considered omnipotent.

Others turn to the established codes, reminding those responsible for the care of patients that they must do whatever is in their power to save a life. Their argument is that health professionals cannot honor their pledge and still believe that euthanasia is justified. If terminally ill patients are kept alive, there is at least a chance of finding a cure that might be useful to them. Opponents of euthanasia feel that legalizing it would destroy the bonds of trust between doctor and patient. How would sick individuals feel if they could not be sure that their physician and nurse would try everything possible to cure them, knowing that if their condition worsened, they would just lose faith and decide that death would be better? Opponents of euthanasia also question whether it will be truly beneficial to the suffering person or will only be a means to relieve the agony of the family. They believe that destroying life (no matter how minimal) merely to ease the emotional suffering of others is indeed unjust.

Many fear that if euthanasia is legalized, it will be difficult to define and develop clear-cut guidelines that will serve as the basis for euthanasia to be carried out. Furthermore, once any form of euthanasia is accepted by society, its detractors fear that many other problems will arise. Even the acceptance of passive euthanasia could, if carried to its logical conclusion, be applied in state hospitals and institutions for the mentally handicapped and the elderly. Such places currently house thousands of people who have neither hope nor any prospect of a life that even approaches normality. Legalization of passive euthanasia could prompt an increased number of suits by parents seeking to end the agony of incurably afflicted children or by children seeking to shorten the suffering of aged and terminally ill parents. In Nazi Germany, for example, mercy killing was initially practiced to end the suffering of the terminally ill. Eventually, however, the practice spread so even persons with the slightest deviation from the norm (e.g., the mentally ill, minority groups such as Jews and others) were terminated. Clearly, the situation is delicate and thought provoking.

2.5 TAKING CONTROL

Medical care decisions can be tremendously difficult. They often involve unpleasant topics and arise when we are emotionally and physically most vulnerable. Almost always these choices involve new medical information that feels alien and can seem overwhelming. In an attempt to assist individuals to make these decisions, it is often helpful to follow these steps:

1. Obtain all the facts—that is, clarify the medical facts of the situation.
2. Understand all options and their consequences.
3. Place a value on each of the options based upon your own set of personal values.

A LIVING WILL

TO MY FAMILY, MY PHYSICIAN, MY CLERGYMAN, MY LAWYER:

If the time comes when I can no longer take part in decisions about my own future, let this statement stand as testament of my wishes: If there is no reasonable expectation of my recovery from physical or mental disability, I request that I be allowed to die and not be kept alive by artificial means or heroic measures. Death is as much a reality as birth, growth, maturity, and old age—it is the one certainty. I do not fear death as much as I fear the indignity of deterioration, dependence, and hopeless pain. I ask that drugs be mercifully administered to me for the terminal suffering even if they hasten the moment of death. This request is made after careful consideration. Although this document is not legally binding, you who care for me will, I hope, feel morally bound to follow its mandate. I recognize that it places a heavy burden of responsibility upon you, and it is with the intention of sharing that responsibility and of mitigating any feelings of guilt that this statement is made.

Signed _____

Date _____

Witnessed by _____

The three-step facts/options/values path concerns the "how" of decisions, but equally important is the "who." Someone must make every single medical decision. Ideally it will be made by the person most intimately involved: the patient. Very often, however, it is made by someone else—spouse, family, physician—or a group of those people acting on behalf of the patient. It is, therefore, important to recognize the four concentric circles of consent:

- The first, and primary, circle is the patient.
- The second circle is the use of advance directives—that is, choosing in advance through the use of such documents as the living will.
- The third circle is others deciding for the patient—that is, the move from personal control to surrogate control.
- The fourth and final circle is the courts and bureaucrats. It is the arena of last resort where our society has decreed that we go when the patient may be incapacitated, where there is no clear advance directive, and where it is not clear who should make the decision.

These three steps and four circles are simply attempts to impose some order on the chaos that is medical decision making. They can help individuals take control.

2.6 HUMAN EXPERIMENTATION

Medical research has long held an exalted position in our modern society. It has been acclaimed for its significant achievements that range from the development of the Salk and Sabin vaccines for polio to the development of artificial organs. In order to determine their effectiveness and value, however, these new drugs and medical devices eventually are used on humans. The issue is, therefore, not only whether humans should be involved in clinical studies designed to benefit themselves or their fellow humans but also clarifying or defining more precisely the conditions under which such studies are to be permitted.

For example, consider the case of a 50-year-old female patient suffering from severe coronary artery disease. What guidelines should be followed in the process of experimenting with new drugs or devices that may or may not help her? Should only those procedures viewed as potentially beneficial to her be tried? Should experimental diagnostic procedures or equipment be tested on this patient to evaluate their effectiveness when compared to more accepted techniques, even though they will not be directly beneficial to the patient?

On the other hand, consider the situation of conducting research on the human fetus. This type of research is possible as a result of the legalization of abortion in the United States, as well as the technological advances that have made fetal studies more practical than in the past. Under what conditions should medical research be conducted on these subjects? Should potentially hazardous drugs be given to women planning to have abortions to determine the effect of these drugs on the fetus? Should the fetus, once aborted, be used in any experimental studies? Although these questions are difficult to answer, clinical researchers responsible for the well-being of their patients must face the moral issues involved in testing new equipment and procedures and at the same time safeguard the individual rights of their patients.

CASE STUDY: NEONATAL INTENSIVE CARE UNIT (NICU)

Throughout time, low birth weight, oftentimes arising from premature birth, has been a major factor affecting infant survival. Underweight infants, who are typically classified as either low birth weight (LBW) (less than 1,500 g) or very low birth weight (VLBW) (less than 1,000 g), must be treated with the utmost caution and care in order to maximize their chances of survival. Advances in premature-infant medical care, such as improved thermoregulation and ventilation techniques, have greatly decreased the mortality rate among LBW and VLBW infants. Included in these advances was the creation of the NICU (Figure 2.2), where all the necessary equipment needed to sustain the life of the child could be kept conveniently in close proximity to one another.

One of the most important devices used in the NICU is the incubator. This device, typically molded of see-through plastic, is used to stabilize the body temperature of the infant. In essence, the incubator allows the medical staff to keep the newborn warm without having to wrap it in

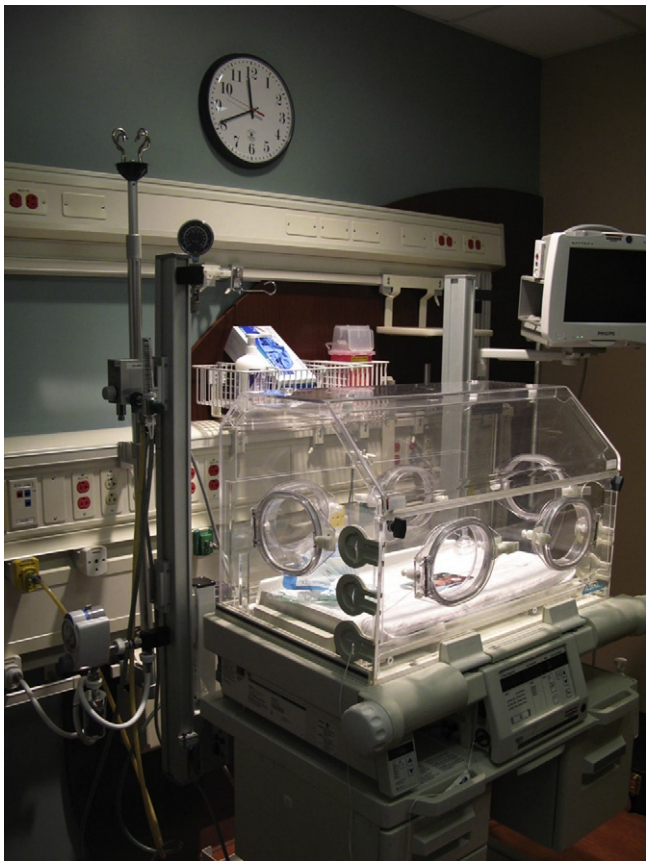

FIGURE 2.2 A Neonatal Intensive Care Unit. *Courtesy of http://www.pediatrics.ucsd.edu/Divisions/Neonatology/Pictures/Image%20Library/NICU%20Bed.jpg.*

blankets. The incubator also aids in preventing infection, as well as in stabilizing the humidity of the child's environment. By keeping the temperature and humidity levels of the newborn's environment static, the baby remains well hydrated and water loss is kept to a minimum.

A complication that many preterm infants suffer from is the inability to breathe normally on their own. The child may be completely unable to breathe for himself, or he may suffer from a condition known as apnea, where the breathing pattern is either aperiodic or irregular.

In these cases, children susceptible to an apneic event are closely monitored so if they stop breathing, nurses can rush to the bedside and wake them up. However, it is often minutes before the nurse can arrive at the scene. To facilitate the process of waking the infant experiencing an apneic event, biomedical engineers developed a tactile vibrator that when triggered by such an event vibrates against the infant's foot and wakes her. In order to prove that the device is effective and safe, a human experiment must be initiated. In this case, the following questions need to be resolved:

1. Who is responsible for proposing the conduction of this study?
2. What should the process of approval of such a study include?
3. What should the policy be related to informed consent?
4. Should changes that were made in the device during the course of the study, which would alter the nature of the initially proposed device, be allowed?

2.7 DEFINITION AND PURPOSE OF EXPERIMENTATION

One may ask, what exactly constitutes a human experiment? Although experimental protocols may vary, it is generally accepted that human experimentation occurs whenever the clinical situation of the individual is consciously manipulated to gather information regarding the capability of drugs and devices. In the past, experiments involving human subjects have been classified as either therapeutic or nontherapeutic. A *therapeutic experiment* is one that may have direct benefit for the patient, while the goal of *nontherapeutic research* is to provide additional knowledge without direct benefit to the person. The central difference is a matter of intent or aim rather than results.

Throughout medical history, there have been numerous examples of therapeutic research projects. The use of nonconventional radiotherapy to inhibit the progress of a malignant cancer, of pacemakers to provide the necessary electrical stimulation for proper heart function, or of artificial kidneys to mimic nature's function and remove poisons from the blood were all, at one time, considered novel approaches that might have some value for the patient. In the process, they were tried and found not only to be beneficial for the individual patient but also for humankind.

Nontherapeutic research has been another important vehicle for medical progress. Experiments designed to study the impact of infection from the hepatitis virus or the malarial parasite or the procedures involved in cardiac catheterization have had significant impacts on the advancement of medical science and the ultimate development of appropriate medical procedures for the benefit of all humans.

In the mid-1970s, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research offered the terms *practice* and *research* to replace the

conventional therapeutic and nontherapeutic distinction just mentioned. Quoting the commission, Alexander Capron in 1986 wrote the following:

> The term *practice* refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. In the medical sphere, practices usually involve diagnosis, preventive treatment, or therapy; in the social sphere, practices include governmental programs such as transfer payments, education, and the like.
>
> By contrast, the term *research* designates an activity designed to test a hypothesis, to permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, or statements of relationships). In the polar cases, then, practice uses a proven technique in an attempt to benefit one or more individuals, while research studies a technique in an attempt to increase knowledge.

Although the practice/research dichotomy has the advantage of not implying that therapeutic activities are the only clinical procedures intended to benefit patients, it is also based on intent rather than outcome. Interventions are "practices" when they are proven techniques intended to benefit the patient, while interventions aimed at increasing generalizable knowledge constitute research. What about those interventions that do not fit into either category?

CASE STUDY: THE ARTIFICIAL HEART

In the early 1980s, a screening committee had been set up to pick the first candidate for the "Jarvik 7," a new (at the time) artificial heart (Figure 2.3). It was decided that the first recipient had to be someone so sick that death was imminent. It was thought unethical to pick someone who might have another year to live when the artificial heart might well kill the patient immediately.

FIGURE 2.3 The Jarvik-7 artificial heart, 1985. *Courtesy of http://www.smithsonianlegacies.si.edu/objectdescription.cfm?ID=172.*

1. Is this an example of nonvalidated practice?
2. Is informed consent still required?

   A week after the operation, Barney Clark began having seizures from head to toe. Suffering a seizure, Clark's unconscious body quivered for several hours. The seizures and spells of mental confusion continued throughout the next months. As a result, Clark expressed a desire to die. Although he did issue a positive statement during a videotaped interview, Clark was not a happy man, tethered to a huge machine, barely conscious, and in some pain. In March 1983, Barney Clark died of multiple organ collapse.

3. Discuss in detail the notions of "criteria for success" and quality of life in this case.
4. Barney Clark suffered a great deal. In response to this, who should be the responsible party in deciding what is right for the patient? When both sides hope for positive results, is it possible to make an unbiased decision based on what's best for the patient?

One such intervention is "nonvalidated practice," which may encompass prevention as well as diagnosed therapy. The primary purpose of the use of a nonvalidated practice is to benefit the patient while emphasizing that it has not been shown to be safe and efficacious. For humans to be subjected to nonvalidated practice, they must be properly informed and give their consent.

2.8 INFORMED CONSENT

Informed consent has long been considered by many to be the most important moral issue in human experimentation. It is the principal condition that must be satisfied in order for human experimentation to be considered both lawful and ethical. All adults have the legal capacity to give medical consent (unless specifically denied through some legal process). As a result, issues concerning legal capability are usually limited to minors. Many states, if not all, have some exceptions that allow minors to give consent.

Informed consent is an attempt to preserve the rights of individuals by giving them the opportunity for self-determination—that is, to determine for themselves whether they wish to participate in any experimental effort. In 1964, the World Medical Association (WMA) in Finland endorsed a code of ethics for human experimentation as an attempt to provide some guidelines in this area. In October 2000, the 52nd WMA General Assembly in Edinburgh, Scotland, revised these guidelines.

Because it is often essential to use the results obtained in human experiments to further scientific knowledge, the World Medical Association prepared the following recommendations to serve as a guide to physicians all over the world. However, it is important to point out that these guidelines do not relieve physicians, scientists, and engineers from criminal, civil, and ethical responsibilities dictated by the laws of their own countries.

2.8.1 Basic Principles

- Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.

- The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol, which should be transmitted to a specially appointed independent committee for consideration, comment, and guidance.
- Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.
- Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
- Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.
- The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
- Doctors should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Doctors should cease any investigation if the hazards are found to outweigh the potential benefits.
- In publication of the results of his or her research, the doctor is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.
- In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The doctor should then obtain the subject's freely-given informed consent, preferably in writing.
- When obtaining informed consent for the research project, the doctor should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case, the informed consent should be obtained by a doctor who is not engaged in the investigation and who is completely independent of this official relationship.
- In the case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation.
- The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

2.8.2 Medical Research Combined with Professional Care

- In the treatment of the sick person, the doctor must be free to use a new diagnostic and therapeutic measure if in his or her judgment it offers hope of saving life, reestablishing health, or alleviating suffering.
- The potential benefits, hazards, and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.
- In any medical study, every patient—including those of a control group, if any— should be assured of the best-proven diagnostic and therapeutic method.
- The refusal of the patient to participate in a study must never interfere with the doctor-patient relationship.
- If the doctor considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee.
- The doctor can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

2.8.3 Nontherapeutic Biomedical Research Involving Human Subjects

- In the purely scientific application of medical research carried out on a human being, it is the duty of the doctor to remain the protector of the life and health of that person on whom biomedical research is being carried out.
- The subjects should be volunteers—that is, either healthy persons or patients for whom the experimental design is not related to the patient's illness.
- The investigator or the investigating team should discontinue the research if in his/her or their judgment it may, if continued, be harmful to the individual.
- In research on humans, the interest of science and society should never take precedence over considerations related to the well-being of the subject.

These guidelines generally converge on six basic requirements for ethically sound human experimentation. First, research on humans must be based upon prior laboratory research and research on animals, as well as upon established scientific fact, so the point under inquiry is well focused and has been advanced as far as possible by nonhuman means. Second, research on humans should use tests and means of observation that are reasonably believed to be able to provide the information being sought by the research. Methods that are not suited for providing the knowledge sought are pointless and rob the research of its scientific value. Third, research should be conducted only by persons with the relevant scientific expertise. Fourth, all foreseeable risks and reasonably probable benefits, to the subject of the investigation and to science, or more broadly to society, must be carefully assessed, and the comparison of those projected risks and benefits must indicate that the latter clearly outweighs the former. Moreover, the probable benefits must not be obtainable through other less risky means. Fifth, participation in research should be based on informed and voluntary consent. Sixth, participation by a subject in an experiment should be halted immediately if the subject finds continued participation undesirable or a prudent investigator has cause to believe that the experiment is likely to result in

injury, disability, or death to the subject. Conforming to conditions of this sort probably does limit the pace and extent of medical progress, but society's insistence on these conditions is its way of saying that the only medical progress truly worth having must be consistent with a high level of respect for human dignity. Of these conditions, the requirement to obtain informed and voluntary consent from research subjects is widely regarded as one of the most important protections.

A strict interpretation of the criteria mentioned above for subjects automatically rules out whole classes of individuals from participating in medical research projects. Children, the mentally retarded, and any patient whose capacity to think is affected by illness are excluded on the grounds of their inability to comprehend exactly what is involved in the experiment. In addition, those individuals having a dependent relationship to the clinical investigator, such as the investigator's patients and students, would be eliminated based on this constraint. Since mental capacity also includes the ability of subjects to appreciate the seriousness of the consequences of the proposed procedure, this means that even though some minors have the right to give consent for certain types of treatments, they must be able to understand all the risks involved.

Any research study must clearly define the risks involved. The patient must receive a total disclosure of all known information. In the past, the evaluation of risk and benefit in many situations belonged to the medical professional alone. Once made, it was assumed that this decision would be accepted at face value by the patient. Today, this assumption is not valid. Although the medical staff must still weigh the risks and benefits involved in any procedure they suggest, it is the patient who has the right to make the final determination. The patient cannot, of course, decide whether the procedure is medically correct, since that requires more medical expertise than the average individual possesses. However, once the procedure is recommended, the patient then must have enough information to decide whether the hoped-for benefits are sufficient to risk the hazards. Only when this is accomplished can a valid consent be given.

Once informed and voluntary consent has been obtained and recorded, the following protections are in place:

- It represents legal authorization to proceed. The subject cannot later claim assault and battery.
- It usually gives legal authorization to use the data obtained for professional or research purposes. Invasion of privacy cannot later be claimed.
- It eliminates any claims in the event that the subject fails to benefit from the procedure.
- It is defense against any claim of an injury when the risk of the procedure is understood and consented to.
- It protects the investigator against any claim of an injury resulting from the subject's failure to follow safety instructions if the orders were well explained and reasonable.

CASE STUDY: CONFIDENTIALITY, PRIVACY, AND CONSENT

Integral to the change currently taking place in the United States health care industry is the application of computer technology to the development of a health care information system. Most major hospitals in the United States have now updated their systems to entirely electronic databases. Patient medications are scheduled and followed by a nurse on a computer module present

FIGURE 2.4 MRI scans are just one of the PPI elements available on electronic databases. *Courtesy of http://images.medicinenet.com/images/SlideShow/dementia_s21_mri_doctor.jpg.*

in every hospital room. MRI scans (Figure 2.4) are no longer printed in film but are uploaded to the patient's file, where physicians with proper approval can access the images. Entire medical histories are stored on patient databases.

1. Discuss the benefits of the electronic system and the potential risks.
2. Discuss in detail where and how the issue of consent to access should be handled. While access to the patient information database is limited to accredited physicians and employees, the issue of illegal access from the inside is a prominent one. Hospital employees with access, be they physicians or researchers, may be capable of accessing family accounts or those of friends. With a paper system, protected patient information (PPI) had the potential to be leaked as well via lost files and irresponsible handling. With the electronic system, however, more intentional breach of privacy may be possible to those with access to the system.
3. How can a hospital employee with a medical record on the system be guaranteed privacy from colleagues?
4. Should patients be allowed to decide personally whether their information is stored electronically? Would an integrated system function efficiently?

Nevertheless, can the aims of research ever be reconciled with the traditional moral obligations of physicians? Is the researcher/physician in an untenable position? Informed and voluntary consent once again is the key only if subjects of an experiment agree to participate in the research. What happens to them during and because of the experiment is then a product of their own decision. It is not something that is imposed on them but rather, in a very real sense, something they elected to have done to themselves. Because their autonomy is thus respected, they are not made a mere resource for the benefit of others. Although they may suffer harm for the benefit of others, they do so of their own volition as a result of the exercise of their own autonomy, rather than as a result of having their autonomy limited or diminished.

For consent to be genuine, it must be truly voluntary and not the product of coercion. Not all sources of coercion are as obvious and easy to recognize as physical violence.

A subject may be coerced by fear that there is no other recourse for treatment, by the fear that nonconsent will alienate the physician on whom the subject depends for treatment, or even by the fear of disapproval of others. This sort of coercion, if it truly ranks as such, is often difficult to detect and, in turn, to remedy.

Finally, individuals must understand what they are consenting to do. Therefore, they must be given information sufficient to arrive at an intelligent decision concerning whether to participate in the research. Although a subject need not be given all the information a researcher has, it is important to determine how much should be provided and what can be omitted without compromising the validity of the subject's consent. Another difficulty lies in knowing whether the subject is competent to understand the information given and to render an intelligent opinion based upon it. In any case, efforts must be made to ensure that sufficient relevant information is given and that the subject is sufficiently competent to process it. These are matters of judgment that probably cannot be made with absolute precision and certainty, but rigorous efforts must be made in good faith to prevent research on humans from involving gross violations of human dignity.

2.9 REGULATION OF MEDICAL DEVICE INNOVATION

The Food and Drug Administration (FDA) is the sole federal agency charged by Congress with regulating medical devices to ensure their safety and effectiveness. Unlike food and drugs, which have been regulated by the FDA since 1906, medical devices first became subject to FDA regulation in 1938. At that time, the FDA's major concern was to ensure that legitimate medical devices were in the marketplace and were truthfully labeled, not misbranded. Over time, the scope of FDA review of medical devices has evolved, as has the technology employed by medical devices). The first substantive legislative attempt to address the premarket review of all medical devices occurred with the Medical Device Amendment of 1976 (Pub. L. No. 94-295, 90 Stat. 539). This statute requires approval from the FDA before new devices are marketed and imposes requirements for the clinical investigation of new medical devices on human subjects. For details related to the FDA process, visit http://www.fda.gov/.

The FDA is organized into five major program centers: the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, the Center for Food Safety and Applied Nutrition, the Center for Veterinary Medicine, and the Center for Devices and Radiological Health (CDRH). Each FDA program center has primary jurisdiction over a different subject area. According to the FDA, the CDRH is responsible for ensuring the safety and effectiveness of medical devices and eliminating unnecessary human exposure to man-made radiation from medical, occupational, and consumer products.

The CDRH has six distinct offices: the Office of Systems and Management, the Office of Compliance, the Office of Science and Technology, the Office of Health and Industry Programs, the Office of Surveillance and Biometrics, and the Office of Device Evaluation (ODE). The ODE has several principal functions, including the following:

- Advising the CDRH director on all premarket notification 510(k) submissions, premarket approvals (PMAs), device classifications, and investigational device exemptions (IDEs).

- Planning, conducting, and coordinating CDRH actions regarding approval, denial, and withdrawals of 510(k)s, PMAs, and IDEs.
- Ongoing review, surveillance, and medical evaluation of the labeling, clinical experience, and required reports submitted by sponsors of approval applications.
- Developing and interpreting regulations and guidelines regarding the classification of devices, 510(k)'s, PMAs, and IDEs.
- Participating in the development of national and international consensus standards.

Everyone who develops or markets a medical device will likely have multiple interactions with ODE before, during, and after the development of a medical device.

In principle, if a manufacturer makes medical claims about a product, it is considered a device, and may be subject to FDA pre- and postmarket regulatory controls (Figure 2.5). The device definition distinguishes a medical device from other FDA-regulated products, such as drugs. According to the FDA, a medical device is:

> An instrument, apparatus, machine, contrivance, implant, in vitro reagent, or other similar or related article intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals OR intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its primary intended purposes through chemical action or is not dependent upon being metabolized.

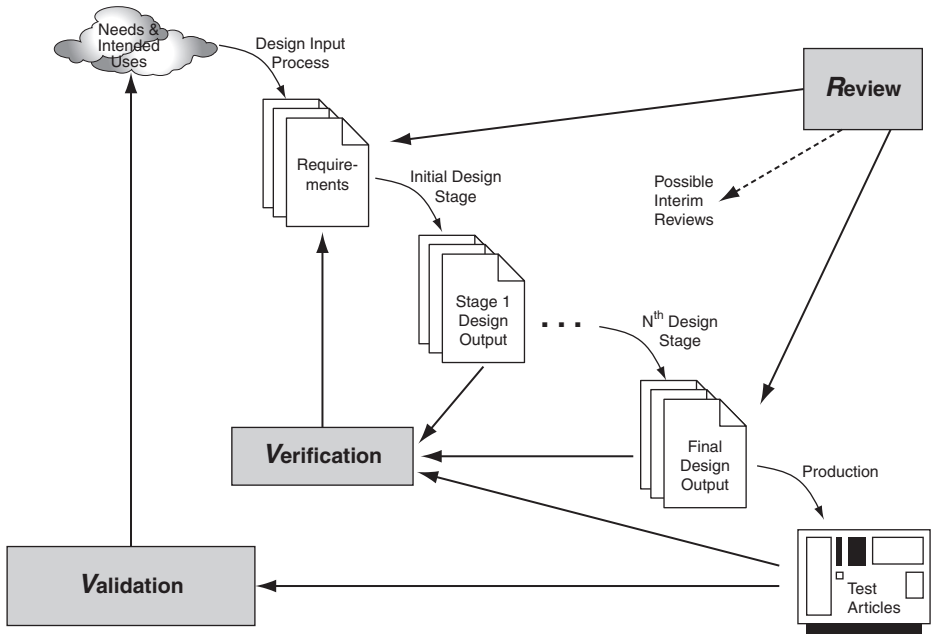

FIGURE 2.5 The purpose of the regulatory process is to conduct product review to ensure (1) device safety and effectiveness, (2) quality of design, and (3) surveillance to monitor device quality. Therefore, the review process results in verification and validation of the medical device.

2.10 MARKETING MEDICAL DEVICES

The four principal routes to marketing a medical device in the United States are as follows.

Premarket Approval (PMA)

A marketing approach for high-risk (Class III) medical devices must be accomplished through a PMA unless the device can be marketed through the 510(k) process (see following). The PMA hinges on the FDA determining that the medical device is safe and effective. The PMA process can be quite costly. The collection of the data required for a PMA may costs hundreds of thousands, if not several million, dollars. Moreover, the timeline for a PMA applicant to collect the requisite data could take several years. However, an approved PMA is akin to a private license granted to the applicant to market a particular medical device, because other firms seeking to market the same type of device for the same use must also have an approved PMA.

Investigational Device Exemption (IDE)

The IDE is an approved regulatory mechanism that permits manufacturers to receive an exemption for those devices solely intended for investigational use on human subjects (clinical evaluation). Because an IDE is specifically for clinical testing and not commercial distribution, the FDCA authorizes the FDA to exempt these devices from certain requirements that apply to devices in commercial distribution. The clinical evaluation of all devices may not be cleared for marketing, unless otherwise exempt by resolution, requires an IDE. An IDE may be obtained either by an institutional review board (IRB), or an IRB and the FDA.

Product Development Protocol (PDP)

An alternative to the IDE and PMA processes for Class III devices subject to premarket approval, the PDP is a mechanism allowing a sponsor to come to early agreement with the FDA as to what steps are necessary to demonstrate the safety and effectiveness of a new device. In the years immediately subsequent to the enactment of the Medical Device Amendment, the FDA did not focus its energies on the PDP but worked to effectively implement the major provisions of the Amendment, including device classification systems, and the 510(k) and PMA processes.

510(k) Notification

Unless specifically exempted by federal regulation, all manufacturers are required to give the FDA 90 days' notice before they intend to introduce a device to the U.S. market by submitting a 510(k). During that 90-day period, the FDA is charged with determining whether the device is or is not substantially equivalent to a pre-Amendment device. The premarket notification is referred to in the industry as a 510(k) because 510(k) is the relevant section number of the FDCA. The 510(k) is used to demonstrate that the medical device is or is not substantially equivalent to a legally marketed device.

With respect to clinical research on humans, the FDA distinguishes devices into two categories: devices that pose significant risk and those that involve insignificant risk. Examples of the former included orthopedic implants, artificial hearts, and infusion pumps.

Examples of the latter include various dental devices and contact lenses. Clinical research involving a significant risk device cannot begin until an institutional review board (IRB) has approved both the protocol and the informed consent form and the FDA itself has given permission. This requirement to submit an IDE application to the FDA is waived in the case of clinical research where the risk posed is insignificant. In this case, the FDA requires only that approval from an IRB be obtained certifying that the device in question poses only insignificant risk. In deciding whether to approve a proposed clinical investigation of a new device, the IRB and the FDA must determine the following:

1. That risk to subjects is minimized.
2. That risks to subjects are reasonable in relation to anticipated benefit and knowledge to be gained.
3. That subject selection is equitable.
4. That informed consent materials and procedures are adequate.
5. That provisions for monitoring the study and protecting patient information are acceptable.

The FDA allows unapproved medical devices to be used without an IDE in three types of situations: feasibility studies, emergency use, and treatment use.

2.11 ETHICAL ISSUES IN FEASIBILITY STUDIES

In a feasibility study, or "limited investigation," human research involving the use of a new device would take place at a single institution and involve no more than ten human subjects. The sponsor of a limited investigation is required to submit to the FDA a "Notice of Limited Investigation," which includes a description of the device, a summary of the purpose of the investigation, the protocol, a sample of the informed consent form, and a certification of approval by the responsible medical board. In certain circumstances, the FDA could require additional information or require the submission of a full IDE application or suspend the investigation.

Investigations of this kind are limited to (1) investigations of new uses for existing devices, (2) investigations involving temporary or permanent implants during the early developmental stages, and (3) investigations involving modification of an existing device.

To comprehend adequately the ethical issues posed by clinical use of unapproved medical devices outside the context of an IDE, it is necessary to use the distinctions among practice, nonvalidated practice, and research elaborated upon in the previous pages. How do those definitions apply to feasibility studies?

Clearly, the goal of the feasibility study, which is a generalizable knowledge, makes it an instance of research rather than practice. Manufacturers seek to determine the performance of a device with respect to a particular patient population in an effort to gain information about its efficacy and safety. Such information is important in order to determine whether further studies (animal or human) need to be conducted, whether the device needs modification before further use, and the like. The main difference between using an unapproved device in a feasibility study and using it under the terms of an IDE is that the former would be subject to significantly less intensive FDA review than the latter. This, in turn, means

that the responsibility for ensuring that the use of the device is ethically sound would fall primarily to the IRB of the institution conducting the study.

The ethical concerns posed here can be best comprehended only with a clear understanding of what justifies research in the first place. Ultimately, no matter how much basic research and animal experimentation has been conducted on a given device, the risks and benefits it poses for humans cannot be adequately determined until it is actually used on humans. The benefit of research on humans lies primarily in the generalizable information that is provided. This information is crucial to medical science's ability to generate new modes of medical treatment that are both efficacious and safe. Therefore, one condition for experimentation to be ethically sound is that it must be scientifically sound.

Although scientific soundness is a necessary condition of ethically sound research on humans, it is not of and by itself sufficient. The human subjects of such research are at risk of being mere research resources—that is, having value only for the ends of the research. Human beings are not valuable wholly or solely for the uses to which they can be put. They are valuable simply by being the kinds of entities they are. To treat them as such is to respect them as people. Treating individuals as people means respecting their autonomy. This requirement is met by ensuring that no competent person is subjected to any clinical intervention without first giving voluntary and informed consent. Furthermore, respect for people means that the physician will not subject a human to unnecessary risks and will minimize the risks to patients in required procedures.

Much of the scrutiny that the FDA imposes upon use of unapproved medical devices in the context of an IDE addresses two conditions of ethically sound research: Is the experiment scientifically sound? and Does it respect the rights of the human subjects involved? Medical ethicists argue that decreased FDA scrutiny will increase the likelihood that either or both of these conditions will not be met. This possibility exists because many manufacturers of medical devices are, after all, commercial enterprises, companies that are motivated to generate profit and thus to get their devices to market as soon as possible with as little delay and cost as possible. These self-interest motives are likely, at times, to conflict with the requirements of ethically sound research and thus to induce manufacturers to fail to meet these requirements. Profit is not the only motive that might induce manufacturers to contravene the requirements of ethically sound research on humans. A manufacturer may sincerely believe that its product offers great benefit to many people and be prompted to take shortcuts that compromise the quality of the research. Whether the consequences being sought by the research are desired for reasons of self-interest, altruism, or both, the ethical issue is the same. Research subjects may be placed at risk of being treated as mere objects rather than as people.

What about the circumstances under which feasibility studies would take place? Are these not sufficiently different from the "normal" circumstances of research to warrant reduced FDA scrutiny? As just noted, manufacturers seek to engage in feasibility studies in order to investigate new uses of existing devices, to investigate temporary or permanent implants during the early developmental stages, and to investigate modifications to an existing device. As also noted, a feasibility study would take place at only one institution and would involve no more than ten human subjects. Given these circumstances, is the sort of research that is likely to occur in a feasibility study less likely to be scientifically sound or to fail to respect people than normal research upon humans in "normal" circumstances?

Research in feasibility studies would be done on a very small subject pool, and the harm of any ethical lapses would likely affect fewer people than if such lapses occurred under more usual research circumstances. Yet even if the harm done is limited to ten or fewer subjects in a single feasibility study, the harm is still ethically wrong. To wrong ten or fewer people is not as bad as to wrong in the same way more than ten people, but it is to engage in wrongdoing nonetheless.

Are ethical lapses more likely to occur in feasibility studies than in studies that take place within the requirements of an IDE? Although nothing in the preceding discussion provides a definitive answer to this question, it is a question to which the FDA should give high priority. The answer to this question might be quite different when the device at issue is a temporary or permanent implant than when it is an already approved device being put to new uses or modified in some way. Whatever the contemplated use under the feasibility studies mechanism, the FDA would be ethically advised not to allow this kind of exception to IDE use of an unapproved device without a reasonably high level of certainty that research subjects would not be placed in greater jeopardy than in "normal" research circumstances.

2.12 ETHICAL ISSUES IN EMERGENCY USE

What about the mechanism for avoiding the rigors of an IDE for emergency use? The FDA has authorized emergency use in instances where an unapproved device offers the only alternative for saving the life of a dying patient. However, what if an IDE has not yet been approved for the device or its use, or an IDE has been approved but the physician who wishes to use the device is not an investigator under the IDE?

The purpose of emergency use of an unapproved device is to attempt to save a dying patient's life under circumstances where no other alternative is available. This sort of use constitutes practice rather than research. Its aim is primary benefit to the patient rather than provision of new and generalizable information. Because this sort of use occurs before the completion of clinical investigation of the device, it constitutes a nonvalidated practice. What does this mean?

First, it means that while the aim of the use is to save the life of the patient, the nature and likelihood of the potential benefits and risks engendered by use of the device are far more speculative than in the sort of clinical intervention that constitutes validated practice. In validated practice, thorough investigation of a device, including preclinical studies, animal studies, and studies on human subjects, has established its efficacy and safety. The clinician thus has a well-founded basis upon which to judge the benefits and risks such an intervention poses for the patient.

It is precisely this basis that is lacking in the case of a nonvalidated practice. Does this mean that emergency use of an unapproved device should be regarded as immoral? This conclusion would follow only if there were no basis upon which to make an assessment of the risks and benefits of the use of the device. The FDA requires that a physician who engages in emergency use of an unapproved device must have substantial reason to believe that benefits will exist. This means that there should be a body of preclinical and animal tests allowing a prediction of the benefit to a human patient.

CASE STUDY: MEDICAL EXPERT SYSTEMS

Expert systems have been developed in various disciplines, including clinical decision making. These systems have been designed to simulate the decision-making skills of physicians. Their adaptability, however, depends on the presence of an accepted body of knowledge regarding the "prescribed path" physicians would take given specific input data. These systems have been viewed as "advisory systems" providing the clinician with suggested/recommended courses of action. The ultimate decision remains with the physician.

Consider one such system designed to monitor drug treatment in a psychiatric clinic. This system, designed and implemented by biomedical engineers working with clinicians, begins by the entry of a specific diagnosis and immediately recommends the appropriate drugs to be considered for the treatment of someone who has that mental disorder (Figure 2.6). The physician selects

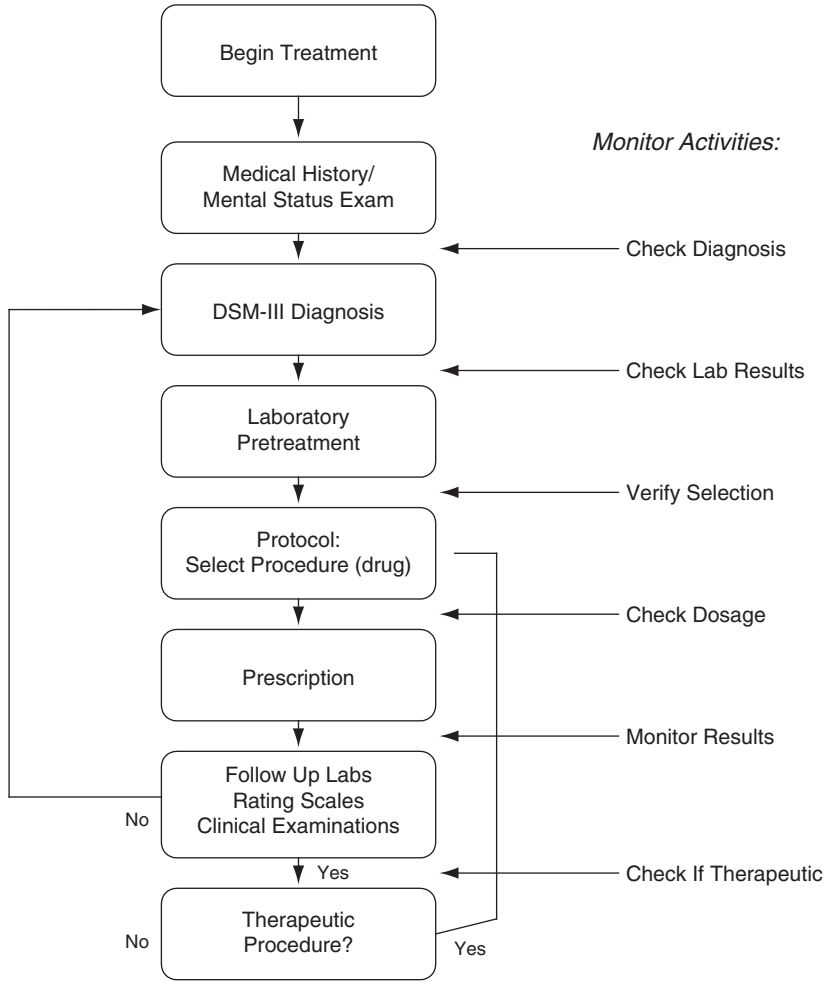

FIGURE 2.6 The drug treatment process followed by clinicians.

one of the recommended drugs and conducts a dose regimen to determine the effectiveness of the drug for the particular patient. During the treatment, blood tests are conducted to ascertain the presence of drug toxicity, and other psychiatric measures obtained to determine if the drug is having the desired effect.

As these data elements are entered, they are compared with standard expected outcomes, and if the outcomes are outside the expected limits, an alert is sent to the physician indicating further action needs to be taken.

In this situation:

1. Who is liable for mistreatment—the clinician, the programmer, or the systems administrator?
2. What constitutes mistreatment?
3. What is the role of the designers of such a system; in other words, what constitutes a successful design?
4. How does the clinic evaluate the performance of a physician using the system, as well as the system itself?

Thus, although the benefits and risks posed by use of the device are highly speculative, they are not entirely speculative. Although the only way to validate a new technology is to engage in research on humans at some point, not all nonvalidated technologies are equal. Some will be largely uninvestigated, and assessment of their risks and benefits will be wholly or almost wholly speculative. Others will at least have the support of preclinical and animal tests. Although this is not sufficient support for incorporating use of a device into regular clinical practice, it may, however, represent sufficient support to justify use in the desperate circumstances at issue in emergency situations. Desperate circumstances can justify desperate actions, but desperate actions are not the same as reckless actions, hence the ethical soundness of the FDA's requirement that emergency use be supported by solid results from preclinical and animal tests of the unapproved device.

A second requirement that the FDA imposes on the emergency use of unapproved devices is the expectation that physicians "exercise reasonable foresight with respect to potential emergencies and . . . make appropriate arrangements under the IDE procedures." Thus, a physician should not "create" an emergency in order to circumvent IRB review and avoid requesting the sponsor's authorization of the unapproved use of a "device." From a Kantian point of view, which is concerned with protecting the dignity of people, this is a particularly important requirement. To create an emergency in order to avoid FDA regulations is to treat the patient as a mere resource whose value is reducible to service to the clinician's goals. Hence, the FDA is quite correct to insist that emergencies are circumstances that reasonable foresight would not anticipate.

Also especially important here is the nature of the patient's consent. Individuals facing death are especially vulnerable to exploitation and deserve greater measures for their protection than might otherwise be necessary. One such measure would be to ensure that the patient, or his legitimate proxy, knows the highly speculative nature of the intervention being offered—that is, to ensure that it is clearly understood that the clinician's estimation of the intervention's risks and benefits is far less solidly grounded than in the case of validated practices. The patient's consent must be based on an awareness that the device whose use is contemplated has not undergone complete and rigorous testing on humans and that

estimations of its potential are based wholly on preclinical and animal studies. Above all, the patient must not be led to believe that the risks and benefits of the intervention are not better understood than they in fact are. Another important point is to ensure that the patient understands all of the options—not simply life or death, but also a life with severely impaired quality. Although desperate circumstances may legitimate desperate actions, the decision to take such actions must rest upon the informed and voluntary consent of the patient, certainly for an especially vulnerable patient.

It is important here for a clinician involved in emergency use of an unapproved device to recognize that these activities constitute a form of practice, albeit nonvalidated, and not research. Hence, the primary obligation is to the well-being of the patient. The patient enters into the relationship with the clinician with the same trust that accompanies any normal clinical situation. Treating this sort of intervention as if it were an instance of research and, thus, justified by its benefits to science and society would be an abuse of this trust.

2.13 ETHICAL ISSUES IN TREATMENT USE

The FDA has adopted regulations authorizing the use of investigational new drugs in certain circumstances where a patient has not responded to approved therapies. This "treatment use" of unapproved new drugs is not limited to life-threatening emergency situations but is also available to treat "serious" diseases or conditions. The FDA has not approved treatment use of unapproved medical devices, but it is possible that a manufacturer could obtain such approval by establishing a specific protocol for this kind of use within the context of an IDE.

The criteria for treatment use of unapproved medical devices would be similar to criteria for treatment use of investigational drugs: (1) the device is intended to treat a serious or life-threatening disease or condition; (2) there is no comparable or satisfactory alternative product available to treat that condition; (3) the device is under an IDE or has received an IDE exemption, or all clinical trials have been completed and the device is awaiting approval; and (4) the sponsor is actively pursuing marketing approval of the investigational device. The treatment use protocol would be submitted as part of the IDE and would describe the intended use of the device, the rationale for use of the device, the available alternatives and why the investigational product is preferable, the criteria for patient selection, the measures to monitor the use of the device and to minimize risk, and technical information that is relevant to the safety and effectiveness of the device for the intended treatment purpose.

Were the FDA to approve treatment use of unapproved medical devices, what ethical issues would be posed? First, because such use is premised on the failure of validated interventions to improve the patient's condition adequately, it is a form of practice rather than research. Second, since the device involved in an instance of treatment use is unapproved, such use would constitute nonvalidated practice. As such, like emergency use, it should be subject to the FDA's requirement that prior preclinical tests and animal studies have been conducted that provide substantial reason to believe that patient benefit will result. As with emergency use, although this does not prevent assessment of the intervention's benefits and risks from being highly speculative, it does prevent assessment from being totally speculative. Here, too, although desperate circumstances can justify desperate action, they do not

justify reckless action. Unlike emergency use, the circumstances of treatment use involve serious impairment of health rather than the threat of premature death. Hence, an issue that must be considered is how serious such impairment must be to justify resorting to an intervention whose risks and benefits have not been solidly established.

In cases of emergency use, the FDA requires that physicians not create an exception to an IDE to avoid requirements that would otherwise be in place. As with emergency use of unapproved devices, the patients involved in treatment uses would be particularly vulnerable patients. Although they are not dying, they are facing serious medical conditions and are thereby likely to be less able to avoid exploitation than patients under less desperate circumstances. Consequently, here too it is especially important that patients be informed of the speculative nature of the intervention and of the possibility that treatment may result in little to no benefit to them.

2.14 THE ROLE OF THE BIOMEDICAL ENGINEER IN THE FDA PROCESS

On November 28, 1991, the *Safe Medical Devices Act of 1990* (Public Law 101-629) went into effect. This regulation requires a wide range of health care institutions, including hospitals, ambulatory-surgical facilities, nursing homes, and outpatient treatment facilities, to report information that "reasonably suggests" the likelihood that the death, serious injury, or serious illness of a patient at that facility was caused or contributed to by a medical device. When a death is device-related, a report must be made directly to the FDA and to the manufacturer of the device. When a serious illness or injury is device-related, a report must be made to the manufacturer or to the FDA in cases where the manufacturer is not known. In addition, summaries of previously submitted reports must be submitted to the FDA on a semiannual basis. Prior to this regulation, such reporting was wholly voluntary. This new regulation was designed to enhance the FDA's ability to learn quickly about problems related to medical devices and supplements the medical device reporting (MDR) regulations promulgated in 1984. MDR regulations require that manufacturers and importers submit reports of device-related deaths and serious injuries to the FDA. The new law extends this requirement to users of medical devices along with manufacturers and importers. This act gives the FDA authority over device-user facilities.

The FDA regulations are ethically significant because by attempting to increase the FDA's awareness of medical device-related problems, it attempts to increase that agency's ability to protect the welfare of patients. The main controversy over the FDA's regulation policies is essentially utilitarian in nature. Skeptics of the law are dubious about its ability to provide the FDA with much useful information. They worry that much of the information generated by this new law will simply duplicate information already provided under MDR regulations. If this were the case, little or no benefit to patients would accrue from compliance with the regulation. Furthermore, these regulations, according to the skeptics, are likely to increase lawsuits filed against hospitals and manufacturers and will require device-user facilities to implement formal systems for reporting device-related problems and to provide personnel to operate those systems. This would, of course, add to the costs of health care and thereby exacerbate the problem of access to care, a situation that many

believe to be of crisis proportions already. In short, the controversy over FDA policy centers upon the worry that its benefits to patients will be marginal and significantly outweighed by its costs.

Biomedical engineers need to be aware of FDA regulations and the process for FDA approval of the use of medical devices and systems. These regulatory policies are, in effect, society's mechanism for controlling the improper use of these devices.

2.15 EXERCISES

1. Explain the distinction between the terms *ethics* and *morality*. Provide examples that illustrate this distinction in the medical arena.
2. Explain the distinction between the terms *beneficence* and *nonmaleficence*, and provide a real-world example of each. Which has been favored by medicine in the ethical sense?
3. Provide three examples of medical moral judgments.
4. What do advocates of the utilitarian school of thought believe?
5. What does Kantianism expect in terms of the patient's rights and wishes?
6. Discuss how the code of ethics for clinical engineers provides guidance to practitioners in the field.
7. Discuss what is meant by brainstem death. How is this distinguished from neocortical death?
8. In response to the Schiavo and Houben case studies, what steps, if any, can be taken to guarantee brain death? Should there be set procedures for determination?
9. Distinguish between active and passive euthanasia, as well as voluntary and involuntary euthanasia. In your view, which, if any, are permissible? Provide your reasoning and any conditions that must be satisfied to meet your approval.
10. Should the federal government be able to require an individual to sign a living will in case of an accident?
11. If the family of a patient in the intensive care unit submits the individual's "living will," should it be honored immediately, or should there be a discussion between physicians and the family? Who should make the decision? Why?
12. What constitutes a human experiment? Under what conditions are they permitted? What safeguards should hospitals have in place?
13. Should animal experimentation be required prior to human experimentation? How does animal research play into the philosophies of nonconsequentialism and utilitarianism?
14. Discuss the relationship between cost (or risk) and benefit in the decision for a patient to participate in a human experiment.
15. In the event of unfavorable and potentially painful results in consented human experimentation, who should be held liable? Why?
16. A biomedical engineer has designed a new sleep apnea monitor. Discuss the steps that should be taken before it is used in a clinical setting.
17. Discuss the distinctions among practice, research, and nonvalidated practice. Provide examples of each in the medical arena.
18. What are the two major conditions for ethically sound research?

19. Informed consent is one of the essential factors in permitting humans to participate in medical experiments. What ethical principles are satisfied by informed consent? What should be done to ensure it is truly voluntary? What information should be given to human subjects?

20. What are the distinctions between feasibility studies and emergency use?

21. In the practice of medicine, health care professionals use medical devices to diagnose and treat patients. Therefore, the clinical staff must not only become knowledgeable and skilled in their understanding of human physiology, but they must also be competent in using the medical tools at their disposal. This requirement often results in litigation when a device fails. The obvious question is, "Who is to blame?"

Consider the case of a woman undergoing a surgical procedure that requires the use of a ground plate—an 8 × 11-inch pad that serves as a return path for any electrical current that comes from electrosurgical devices used during the procedure. As a result of the procedure, this woman received a major burn that seriously destroyed tissue at the site of the ground plate.

(a) Discuss the possible individuals and/or organizations that may have been responsible for this injury.

(b) Outside of seeking the appropriate responsible party, are there specific ethical issues here?

Suggested Readings

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