

A Decision-Making Model for Bioethical Issues

Introduction to Bioethics

Since the middle of the 20th century, rapid improvements in technology have changed the practice of medicine profoundly. The technology often allows physicians to restore or supplant basic bodily functions. Mechanical ventilators, heart pacemakers, kidney dialysis machines, exotic drugs, organ transplantation, and artificial nutrition and hydration are some of the life-extending tools available to the modern practitioner.

Initially, the use of these techniques was seen as altogether positive, a must-do choice for the physician. It was not long, however, before difficult questions surfaced. Just because we *can* maintain a person with artificial ventilation and nutrition, *should* we? Who should answer such a question: the patient, physician, family, nurse, social worker, hospital administrator, insurance company, ethicist, politician?

Since the 1960s, questions like this one have provided us with an entirely new discipline or, more accurately, interdiscipline: bioethics. Bioethics, or biomedical ethics, has become an immensely important topic. Few major hospitals are without an ethics committee to assist patients or health care providers when they need help. Colleges offer courses of study in medical humanities or bioethics. High school students, too, must be aware of the questions bioethicists study.

Paralleling the medical developments described above were striking advances in our understanding of genetics and molecular biology. Genetic knowledge has only recently been applied to specific diseases or patients, but the ethical questions that plague us about any medical technology apply also to medical biotechnology.

How do we decide what is right or wrong, what is better or worse, as medical biotechnology offers us ever more choices? Should everyone be screened to determine who the carriers of recessive alleles for genetic diseases are? Should genetically engineered

products be available to everyone, or should we sometimes screen requests for them (such as requests for human growth hormone)? Who should (and who actually will) have access to a person's DNA fingerprint? Are we on the road to employment and insurance discrimination based on genetic profiles? These are but a few of the ethical questions that can be posed.

The Bioethics Decision-Making Model

In attempting to answer difficult ethical questions, it is helpful to focus on specific cases and follow a step-by-step procedure. Below, you will be presented with specific case studies to analyze and a decision-making model to be used in these analyses. Part of the decision-making process will be to gather any additional background facts you need for evaluating the situation and to find out what sort of ethical standards that apply to your case have been established. Finally, you will make a decision as to the best course of action and justify it in terms of basic ethical principles.

Identifying a dilemma

The case studies we have provided raise bioethical dilemmas. A dilemma exists when there is no "right" course of action in a certain situation but, instead, several options, none of which is wholly acceptable. Ethical dilemmas revolve around trying to find the best solution when no solution is completely good. Not every situation presents a dilemma; many times, the possible courses of action are clearly right or wrong. The following example may clarify what does and does not constitute a dilemma.

Assume that a patient with a certain condition would be an appropriate candidate for a drug research study. The patient's physician places her on this drug without getting her permission. This situation is not a dilemma. It is just plain wrong. Even if the doctor believes the drug will benefit the patient, by all modern

medical standards, the physician has the obligation to get the patient's informed consent to include her in the study. (The Nuremberg Code and the Declaration of Helsinki, two internationally recognized codes of ethics, specifically address the ethics of research using human beings.)

On the other hand, assume that the patient has been given all the information she needs for making a decision. She is told that the drug has the potential to help her but might also have harmful side effects. She sees benefits and costs regardless of which decision she makes. Now we have a dilemma. A dilemma exists when no choice is ideal but all options have benefits and risks that must be carefully assessed.

Once a dilemma has been identified, the next step is to pose the dilemma in the form of a question about a specific case. Often, more than one question can be formulated. You will need to choose one question at a time for analysis, although you may consider several questions, one after the other, about a single case. It is also helpful to categorize the kind of issue being discussed. In the example given previously, the issue might be human research and the question posed could be, "Should the patient agree to be part of the study or not?" Since these discussions are usually very interesting and emotional, it is easy to get off track. The decision-making model presented here reduces that risk.

Basic ethical principles

In order to make ethical decisions, we must agree on some basic guidelines about what constitutes moral conduct. In the field of biomedical ethics, certain guides are well established. The moral-action guides or principles can be divided into four major principles and several secondary ones. These principles are listed below. The terms in parentheses are those used in bioethical literature. You may encounter them in your library work.

Major Ethical Principles

1. Do no harm (nonmaleficence).
2. Do good (beneficence).
3. Do not violate individual freedom (autonomy).
4. Be fair (justice).

Secondary Ethical Principles

1. Tell the truth (truthtelling).
2. Keep your promise (fidelity and promise keeping).
3. Respect confidences (confidentiality).
4. Use the principle of proportionality: risk-benefit ratio (how much harm can be justifiably risked to effect good).

5. Attempt to avoid undesirable exceptions, also known as the wedge principle, the slippery slope, or the camel's nose.

Although these rules are simple, they represent fundamental values associated with respect for human dignity that most people agree to. These are the principles to which you should refer when making and justifying decisions.

Basic steps of the decision-making model

Here is a summary of the steps in the decision-making model. Each step will be explained more fully later on. Begin with a case study.

1. Identify the question you want to address. Usually, for any given case, many questions could be considered. Choose the one you want to explore.
2. Identify the issue you are exploring (i.e., genetic screening, confidentiality, gene therapy, human research subjects, etc.). Naming the issue will help in the search for relevant literature.
3. State the facts in the case. Be sure to avoid inferences.
4. Think of as many possible decisions in the case as you can.
5. Gather additional information as needed.
6. Pick the decision you want to support.
7. State the ethical principle that supports your decision (your claim).
8. Identify an authority that supports your decision. Quote the authority, if possible.
9. Formulate a rebuttal. Under what circumstances would you abandon your claim?
10. How strongly do you believe your claim? What is your level of confidence, the qualifier?
11. "Box up" the case for reporting your decision.
12. Write a prose argument describing the case and your decision.

Rules for classroom discussion

Since the issues discussed in bioethics are controversial, it is important that the following rules of etiquette be observed from the very beginning.

1. Only one person at a time speaks after being recognized by the discussion leader.
2. Treat each other with respect; no name calling. Critique the argument, not the author of the argument.
3. Seek clarity by asking questions.
4. Look for gaps in the data.
5. Recognize your own biases.
6. Be true to your own position; do not jump on the bandwagon.
7. Keep emotions in check; use logic.
8. Do not follow authority blindly (the teacher doesn't know everything).
9. You must have a reason, not just an opinion. You can like pepperoni pizza better than anchovy pizza with no reason. You cannot decide bioethical issues based on opinions.
10. Be open minded and willing to be perplexed.

Example Case Study 1: Frank and Martin

This case shows an ethical dilemma but does not involve medicine or biotechnology. It serves as a useful example of how the decision-making model can be applied to many problems outside the bioethics arena.

Frank is an 11th-grade student at a small public high school that prides itself on its family atmosphere and strong academic reputation. The school has an honor code. Each student agrees to abide by a published list of rules. One part of the code obligates students to report observations of fellow students who may be cheating. A judiciary council composed primarily of students decides what should happen in each case. Frank works hard at school. He has a B+ average and hopes to go to a good college. He also works part-time, runs track, and helps at home with two younger brothers. Both of his parents work. Frank is a close friend of Martin. Martin is very bright and does well in school, although he does not have to put in as much time studying as Frank does. Martin does not have many extracurricular activities or responsibilities. During a history test, Martin notices that Frank appears to be cheating off a note card.

I. Identify the question

Think of as many questions as you can. It may help you to think of questions that start with "Should. . . ."

For example, one question you might ask could be, "Should Martin ask other students if they saw anything?" List as many questions as you can. After you have done so, choose one question for analysis. Remember, you can consider other questions later.

II. Identify the issue

What general problem does the case demonstrate? In this case, it might be cheating or school rules. (Although the principal figures in the case are students, students per se are not the issue.) This step is an attempt to categorize the case in a way that will help you find additional information when you search the bioethical literature.

III. State the facts of the case

What are the facts in the case? Most of us have a tendency to draw conclusions based on some information and then believe that our conclusions are facts, too. Be sure to distinguish between the facts and your inferences. Once the facts have been established, list them in an accurate but concise manner.

IV. List as many possible decisions as you can

What are the possible answers to the question you are addressing? Now is the time to be creative. Think of as many possible answers as you can. At this point, don't worry about which answer is best; that comes later.

V. Gather additional information as needed

Obviously, you don't have access to any additional information about Frank and Martin, but often, background information on the important issues involved in a case study is available. Frank and Martin's case will probably not require gathering additional background information. However, other cases may. For example, in order to weigh the risks and benefits in a case involving use of an experimental drug to treat a patient, you may want to know just how severe the patient's disease is. It might also be appropriate to find out what sort of safety testing a drug must undergo before it is approved for experimental treatment of humans.

The bottom line is that you should be as well informed as possible before you make an ethical decision.

VI. Pick the decision you wish to support

Consider all the possible decisions listed in step IV. Since ethical problems are usually complex, it is important to take time for thoughtful, honest reflection. You must have a reason for the option you choose, and that reason should be related to one of the principles listed at the beginning of this reading.

VII. Identify the ethical principle that supports your decision

An ethically justifiable decision can be based on alternative principles. In a dilemma, adherence to one principle often results in the breach of another; dilemmas exist because principles often conflict. Application of different basic values can lead to different responses to a situation. Part of the decision-making process is realizing to which principle you are giving preference.

For example, someone who believes it is more important in this case to do no harm (principle 1) might make a different decision from someone who believes it is more important to uphold justice (principle 4). Neither person would be wrong. Both are adhering to high moral principles, but their principles are different.

Contrast these decisions to those of a person who decides to do nothing because someone might get angry or because he doesn't want to get involved. Keeping people from getting mad at you or keeping from getting involved are not high moral principles.

VIII. Identify a supporting authority

What experts or authorities would back up our position on this case? Normally, it is appropriate to look to professional codes of ethics. In this case, the honor code itself would be the authority. In bioethical decisions, several codes of ethics are used; these include the Hippocratic Oath, the American Medical Association Code of Ethics, the American Hospital Association's Bill of Rights for Patients, and the American Nursing Association Code of Ethics as well as the Nuremberg and Helsinki statements.

IX. Formulate a rebuttal

Under what circumstances would you change your decision about what to do? Try to imagine a circumstance or new information that could make you change your mind.

X. State your level of confidence in your decision

Use a one- or two-word statement to describe how strongly you believe in the argument you have made for your decision (your claim). One way to assess the strength of the argument is to gauge the likelihood of rebuttal. If a rebuttal is highly unlikely and the rest of the argument makes sense, then the argument is a strong one. Also, if the principle ties the claim and the facts tightly together, then the argument is strong.

Indicate the degree of confidence you have by using one of the following qualifiers or a similar one: "moderately confident," "absolutely confident," or "questionably confident."

XI. Box up the case for reporting

Your teacher will show you how to summarize your case in the box outline provided at the back of the book.

XII. Prepare a prose argument

Write up your argument, using the box as an outline. You should produce a paper that can be understood by someone who is completely unfamiliar with the original case. You should also explain more in the paper than the box can show. For instance, you should elaborate on why you selected the decision you chose and why the ethical principle justifying that decision was most important in this incident.

Example Case Study 2: Mr. Johnson

Mr. Johnson, age 76, was admitted to a medical unit with pneumonia. He had a history of severe emphysema for which he had been hospitalized twice in the past year because of secondary pneumonia. During the evening of the third day of intravenous antibiotic treatment, Mr. Johnson's complexion took on an increasingly bluish tint, and he was short of breath. Because the attending physician was out of town, the physician taking calls was notified by the evening nursing supervisor. The physician found the patient to be severely oxygen deficient. He tried unsuccessfully to reach Mrs. Johnson to notify her of his plan to transfer Mr. Johnson to the intensive care unit for ventilator support. During the process of arranging for the transfer, a nursing assistant said that she thought that Mr. Johnson and his wife had said that they would refuse life support measures if Mr. Johnson ever needed them. No documentation of these comments could be found.

When Mr. Johnson arrived in intensive care, he was anxious, and his breathing was so labored that he could not talk. He shook his head “no” when the physician explained the procedure for inserting a tube to connect him to the ventilator, and he attempted to push the physician away. Mr. Johnson’s competency to make decisions about his treatment was questioned because his arterial blood oxygen was so low. Another unsuccessful attempt was made to reach Mrs. Johnson. Mr. Johnson’s condition deteriorated as the physician and staff deliberated about proceeding with the intubation. Finally, the patient was sedated and placed on the ventilator.

Mrs. Johnson arrived the next morning and was shocked that her husband’s condition had deteriorated so rapidly. She was upset that her husband was on the ventilator, explaining that they had agreed that life support measures would not be used for him. When the on-call physician asked, “What do you want me to do,” Mrs. Johnson replied, “I don’t know.” The physician asked for assistance from the Ethics Committee.

I. Identify the question

What question will you address about this case? List possible questions (“Should . . . ?”), and then select one.

II. Identify the issue

The general category of problem could be called withdrawal of life support or end-of-life decisions or extraordinary means. This step helps in grouping cases and may make it easier to find references in the literature.

III. State the facts of the case

Only the facts as they are known may be used. List the facts in a concise manner, avoiding inferences or conclusions you may have drawn.

IV. List the possible decisions

What are the possible courses of action in this case? List as many as you can without worrying for now about which is best.

V. Gather needed background facts

Obviously, no further information is available about the Johnsons, but you may have other questions. What is emphysema? What is secondary pneumonia? What is arterial blood oxygen, and why would low oxygen levels make a doctor think Mr. Johnson wasn’t competent to make decisions? What is a ventilator? Be sure you have a good understanding of the case before you attempt to make a decision.

VI. Make a decision

VII. Identify the guiding principle

VIII. Cite a supporting authority

As time permits, read about similar cases. What do recognized codes of ethics say about these situations? A list of recognized codes of ethics is given in the discussion of the Frank and Martin example.

IX. Formulate a rebuttal

Under what circumstances would you abandon your decision?

X. State your level of confidence

XI. Box up the case for reporting

Summarize the case and your claim in the box form provided at the back of the book.

XII. Prepare a prose argument

Write up your argument in paragraph form so that someone who has never seen the case before can understand it and the reasons for your decision.

Bioethics Case Study: Gene Therapy

Background Information

Advances in genetic engineering technology offer hope to people afflicted with a number of genetic diseases. Although gene therapy is in its infancy, early studies are encouraging. In the first approved human gene therapy experiment, W. French Anderson is treating the genetic disease called severe combined immunodeficiency disease. Students are usually familiar with the dramatization (starring John Travolta) about the "bubble boy," a young man with this disorder. The disease is caused by the lack of the enzyme adenosine deaminase (ADA).

In 1990, Anderson inserted the correct sequence for ADA into the white blood cells of a young child who was not producing it. As of March 1992, Anderson's patient was producing the enzyme and interacting with the world freely for the first time in her life. In fact, she was one of the children in her preschool who did not get chicken pox during a recent outbreak. Other children have now received similar therapy and are also doing well.

Before this experimental treatment could begin, Anderson's proposal went through extensive review by the Recombinant DNA Advisory Committee at the National Institutes of Health (NIH), the government agency that funds most of the country's biomedical research. In fact, Anderson's proposal was reviewed 15 times. The need for a standard review procedure for proposed human gene therapy experiments was made clear in 1979-1980, when a UCLA researcher tried a human gene therapy experiment on two patients without getting approval from the appropriate review committee at his institution. He was eventually demoted, and his case demonstrated the need for a national policy on human gene therapy experiments.

A standard procedure is now in place, and with Anderson's work as a model, we can expect more and more trials. Several clinical trials for a number of different conditions are now under way.

What is gene therapy, and what ethical issues, if any, does it raise? At first glance, gene therapy, like any medical treatment that proposes to benefit the patient, seems free of any ethical implications. Closer examination raises a number of important questions regarding the acceptability of different kinds of gene therapy. Leroy Walters, of Georgetown University's Kennedy Institute of Bioethics, divided gene therapy into four possible categories.

1. Somatic-cell gene therapy for cure or prevention of disease. *Example:* Insertion of sequence in a person's cells to allow production of an enzyme like ADA.
2. Germ line gene therapy for cure or prevention of disease. *Example:* Insertion of ADA sequence into early embryo or reproductive cells; will affect not only the individual but all his or her offspring.
3. Somatic cell enhancement. *Example:* Insertion of DNA sequence to improve memory, increase height, or increase intelligence; would affect only that individual.
4. Germ line enhancement. *Example:* Insertion of DNA sequence for enhancement into blastocyst, sperm, or egg; would affect future generations.

One of the ongoing issues concerning gene therapy is whether any or all of the four types of manipulation listed above are ethically acceptable. At present, only somatic-cell gene therapy for cure or prevention of serious disease is considered ethically appropriate even by researchers like Dr. Anderson. Germ line therapy (altering disease genes so that the individual will not only be healthy but will pass on the healthy genes to his or her offspring) is considered desirable by some, but the techniques used to alter animal embryos have far too high a failure rate to consider their application to humans at this time. Human germ line therapy will probably be feasible in the future.



Enhancement therapy (whether somatic cell or germ line) is generally viewed as less acceptable. Anderson has stated, "I will argue that a line can and should be drawn to use gene transfer only for the treatment of serious disease, and not for any other purpose. Genetic transfer should never be undertaken in an attempt to enhance or 'improve' human beings." Anderson, a pioneer in this field, has maintained his position since 1980.

Guidelines for Gene Therapy

In considering any application of gene therapy, basic respect for human dignity is, as always, the underlying moral principle. Like any other experimental medical treatment, gene therapy should be used to benefit the patient. Harm should be avoided. Certain factors must be considered. An NIH committee suggested the following items in 1985.

1. What is the disease to be treated?
2. What alternative treatments for the disease exist?
3. What are the potential benefits of gene therapy for human patients?
4. How will patients be selected in a fair and equitable manner?
5. How will a patient's voluntary and informed consent be solicited?
6. How will the privacy of patients and the confidentiality of their medical information be protected?

These six questions address some ethical concerns that have been considered in evaluations of experimental proposals. You may think of additional ones.

Case Study 1: Anne B.

Gaucher's disease, first identified in the late 19th century, is an autosomal recessive disorder. The disease results from the production of a structurally altered form(s) of the enzyme β -glucocerebrosidase, which breaks down a lipidlike substance, glucocerebroside. Failure to properly metabolize this substrate results in its accumulation in the spleen, liver, and bone. The disease varies widely in severity: some afflicted individuals die in early childhood, while others are diagnosed on autopsy after death from other causes at an old age. The severest form (the infantile form) follows a course somewhat similar to that seen in a related lipid disorder, Tay-Sachs disease.

Because of the variation in severity, Gaucher's disease is classified into forms I, II, and III: adult noncerebral, acute neuropathic, and subacute neuropathic, respectively. Studies suggest that these forms of the disease are allelic; that is, they are caused by different mutations within the same gene. The resulting structural defect in the protein is related to the severity of the disease.

The most common of the three types is form I (the least severe adult form). Form I Gaucher's disease is known to occur frequently in Ashkenazic Jews; approximately 1 in 13 members of this population is a carrier (heterozygotes). Patients with type I disorder have about 15% of the enzyme activity of normal individuals. There are estimated to be 20,000 cases in the United States. Although form I Gaucher's disease is the least severe of the three forms of the disease, it, too, varies in severity: some afflicted individuals die in early adulthood, while others live essentially symptom free to old age. Form I Gaucher's disease is therefore subdivided into acute, moderate, and mild courses.

Form I Gaucher's disease may first produce symptoms in a patient's late teens, with an enlarged spleen often being an early sign. Blood studies show reduced platelet, white blood cell, and red blood cell counts. Anemia and enlargement of the spleen may require removal of the spleen. Although this surgery decreases the anemia and relieves abdominal stress, the unmetabolized material is deposited in the bone more rapidly after splenectomy. Bone pain and pathologic fracture may occur.

In 1989, Joan B., age 32, died from the secondary effects of Gaucher's disease. Joan's 23-year-old sister, Anne B., also has the condition. However, she has been receiving enzyme replacement therapy each week since April 1992.

The biotechnology firm Genzyme marketed the β -glucocerebrosidase enzyme in June 1991. Anne receives the enzyme every week by intravenous infusion at the office of her physician. Her physician is considered one of the most knowledgeable practitioners with regard to this particular disorder. The infusion process takes about 4 h each week, including 2 h of travel time. The efficiency of the enzyme replacement therapy is not completely known, but early studies have been very encouraging. There have been no harmful side effects.

Anne recently read about a new experimental treatment that involves removing some of her own cells, treating them with a retrovirus that carries the cor-

rect sequence for glucocerebrosidase, and replacing the cells. The cells should reproduce, creating a colony of cells that make the proper enzyme. The hope is that this treatment could be done several times, resulting in enough cells to produce permanently adequate amounts of normal enzyme. The technology is experimental and there may be risks, some known and some unknown. For instance, since the sequence is added by using a retrovirus, some of Anne's normal DNA might be altered. This treatment is also more expensive than Anne's current treatment. Anne requests the experimental treatment from her physician.

Implementing the decision-making model

First of all, does an ethical dilemma exist? Anne has requested an experimental treatment that may harm her or may help her and improve her quality of life. Should her physician help her get the treatment she wants? Is it medically indicated? Will the treatment do more harm than good, since she is already receiving enzyme replacement therapy? Is her disease as serious as French Anderson says it should be in order to qualify for gene therapy? There are certainly enough questions to indicate that this case does present bioethical issues.

I. Question

Several possible questions are listed above. List as many others as you can think of, and then choose one for consideration.



II. Issue

What is the issue you chose? Experimental treatment? Medical necessity? Something else?

III. Facts

There is a lot of background material in this case. For the box summary, try to select only the information that is necessary for presenting the dilemma. You could reasonably omit background information about Gaucher's disease from the box, for example.

IV. Possible Decisions

List as many alternatives as you can without trying to decide at this time which is best.

V. Additional Information

Do you need additional information to make a good decision? For example, if you are trying to decide whether the doctor should give Anne the treatment, do you need to know more about retroviruses, how they work, and how they might alter Anne's DNA? Do you need more information about Gaucher's disease

to decide whether it is serious enough to warrant gene therapy?

VI. Decision

Choose what you believe to be the best solution to your question.

VII. Principle

Which of the major ethical principles justifies your decision?

VIII. Authority

What experts would back up your option? Find relevant passages in documents such as the Hippocratic Oath, the Nuremberg Statements, and the Patient Bill of Rights.

IX. Rebuttal

Under what circumstances would you abandon your choice?

X. Level of Confidence

How strongly do you believe your position?

XI. Box

Use the outline at the back of the book.

XII. Prose Format

Explain on paper why you chose one option rather than the other and why the principle supports the option. Your written argument should reflect the thinking necessary to construct the box and be complete enough that someone who has never read the case study can understand the situation and your analysis.

Additional case studies follow.

Case Study 2: Bobby K.

Bobby K. is a healthy 10-year-old boy. He is very agile and quick and loves sports. The coach of his city league basketball team has told Bobby's parents that their son's skills on the court are astounding for a child of his age.

Bobby's father, Mr. K., is a healthy man who is 5'3" tall. Bobby's mother is also short, only 5'0". Bobby's pediatrician has predicted that Bobby will attain an adult height of about 5'3" but has emphasized to his parents that he is a normal, healthy boy. Mr. K. remembers being teased constantly about his size and recalls that his lack of height kept him off all the varsity sports teams at his high school. He has often wondered if his shortness is a disadvantage to him in business dealings, too. Mr. and Mrs. K. both anticipate

that their son will be the recipient of more and more pointed teasing as he reaches his teenage years. They also fear that he will not be selected for the basketball team when he reaches junior high or high school.

Bobby's coach has heard of a program at the local university in which gene therapy is being conducted on children who have a disease that results in the inadequate production of growth hormone. The children are being given working copies of the gene for human growth hormone, and the levels of growth hormone in their bodies have increased. These children's growth rates have also increased.

Bobby's coach tells the K. family about what he has heard. Bobby is thrilled, because he might be able to keep playing basketball, maybe even on a professional level. Bobby's parents are more cautious but would like their son to be spared the pain of being much smaller than his classmates.

The K.'s go to Bobby's pediatrician and request that Bobby be given the growth hormone gene therapy.

Using the decision-making model

This case obviously presents many possible questions for consideration. For example,

- Should Bobby's doctor allow him to have the gene therapy?
- Should Bobby's parents let him have the therapy?
- Should Bobby's coach have told the K.'s about the program?

There are probably many background questions you will need to investigate. For example,

- Have there been any studies to determine whether it is safe to give additional growth hormone to normal children?
- What height range is considered normal? How can you tell whether a short person is normal?

Choose a dilemma question for analysis, and use the model to generate a solution.

Case Study from Real Life

This case study also revolves around human growth hormone but concerns administration of the hormone as a drug, not gene therapy. It is a summary of the article "NIH stops enrolling children in growth hormone studies" in *Biotechnology Newswatch*, August 17, 1992.

In 1992, because of questions about the safety and appropriateness of the study, the NIH temporarily stopped doctors from enrolling more children in a study of the effects of growth hormone on healthy short children. Children already in this trial will continue. Without treatment, the boys in this study were expected to reach 5'6" or less and the girls were expected to reach 5'0" or less as adults. Half of the children are being given genetically engineered human growth hormone (the protein, not the gene), and the other half are receiving a placebo. These children do not know that their treatment is a placebo. They will serve as a control group for the children who are receiving the hormone. The physicians hope to learn how much additional growth the hormone produces in healthy short children.

Doctors normally prescribe growth hormone to children who fail to produce enough of it naturally and are expected to reach an adult height of 4'0" or less. The hormone has been on the market for 7 years, and Genentech (one of the two companies in this country that make the hormone) is convinced that no safety problems are associated with long-term use of the hormone.

Scientists who defend the study present several points. One is that many parents obtain human growth hormone for their children on the black market. Another is that studies to determine the safety and efficacy of this treatment for short stature are needed. Another argument is that our society is preoccupied with height and that short stature can cause anxiety and poor self-image to the point that mental health is compromised. One of the scientists who defend the study is Dr. Arthur Levine, scientific director of the National Institute of Child Health and Human Development. At 5'4", Dr. Levine says he probably would have enrolled himself in the study if it had been available to him as a child.

Critics of the study argue that shortness is not a disease and should not be defined as requiring treatment. They question the use of a relatively experimental treatment in healthy children for apparently cosmetic reasons. They are concerned that virtually any cosmetic defect could eventually be redefined as illness.

Using the model

Apply the decision-making model as outlined previously. Some questions that could be asked include the following.

- Should this study be conducted?
- Should a parent enroll a short child in this study?
- Should doctors prescribe growth hormone to short but otherwise normal children?
- Should people be able to make their own decisions about taking growth hormone?

- Should any treatment be available for shortness?
- Should NIH prevent children who want to enroll from participating?

You may be able to think of more questions. Choose one for analysis, using the decision-making model.

Issue:

Question:

Facts

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Authority

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Qualifier

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Principle

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Decision

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Rebuttal

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