

Chapter III

**WHAT ARE THE IMPACTS
OF MEDICAL TECHNOLOGY?**

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At present, many decisions about the development and implementation of new technologies are made on the basis of a limited number of criteria, such as:

- . Technical feasibility: Can the technology be developed, and is it likely to do what it is supposed to do?
- . Safety: Will the technology cause undue harm to its providers or users?
- . Anticipated need or demand: Is the technology worth developing? In the private sector, economic indicators of market size or profitability may be used to estimate demand; estimates of potential need for technologies developed in the public sector may be based on both economic and non-economic factors.

The material presented in chapter II of this report has demonstrated that the impacts of many medical technologies are far broader in scope than these few criteria would imply. The development and eventual use of new medical technologies may have implications for:

- . The patient;
- . The patient's family;
- . The society as a whole (including impacts both on tangible common goods, such as the environment, and on less-tangible factors, such as ethics, cultural values, or demographic variables);
- . The medical care system;
- . The legal and political systems;
- . The economy (including impacts that extend far beyond the burden imposed by the direct cost of the new technology).

Each of these areas is itself complex, and the whole set encompasses a bewilderingly broad array of impacts. To clarify the nature and scope of these impacts, the remainder of this chapter presents—

- . A list of questions that could be used to explore the implications of introducing a new medical technology; ¹
- . Some preliminary questions about the medical aims, technical characteristics, and developmental state of the new technology that must be answered before broader impacts can be considered; and

¹ The questions are drawn from issues raised by the cases in ch. 11, and on material from a variety of other sources (13, 16,30, 43, 74, 91, 104, 123, 140, 142, 194).

- Answers to several of the questions, with reference to the totally implantable artificial heart, z which illustrate the types of information that one might hope to elicit.

PRELIMINARY CONSIDERATIONS:

WHAT ARE THE MEDICAL AIMS, TECHNICAL CHARACTERISTICS, AND DEVELOPMENTAL STATE OF THE TECHNOLOGY IN QUESTION?

- What medical problems is the new medical technology designed to solve, and how severe are these medical problems: Does it diagnose an early form of the disease? Does it make diagnosis more reliable or valid? Does it treat a life-threatening symptom or syndrome? Does it correct an incapacitating but non-lethal condition?

The totally implantable artificial heart is designed to replace the natural heart of patients whose hearts are no longer capable of functioning adequately. The majority of these have ischemic heart disease (that is, heart disease resulting from blockages of the coronary arteries of the heart) and would soon die if untreated.

- How many people are afflicted with the medical problem?

Heart disease is the most common cause of death in the U.S. population. Many heart victims, however, could not successfully be treated by implantation of an artificial heart. From 16,750 to 50,300 people each year are estimated to be candidates for implantation.

- Is the technology a major or minor innovation? Will it radically alter medical practice or will it modify and improve established procedures?

A totally implantable artificial heart will be a major medical innovation. It would provide an entirely new way of treating patients for whom no effective therapy is presently available.

- What knowledge base underlies the proposed technology? How has the technology developed so far? What future knowledge of importance can be anticipated?

Knowledge of the anatomy and physiology of the normal heart, as well as advances in bioengineering, underlie the development. Development so far is the result of 20 years of work to adapt equipment used in open-heart surgery for long-term use. Concerted NIH support for work on the implantable heart may have speeded progress. A left ventricular assist device, or artificial left ventricle, developed largely with NIH support is a major step in the development of a totally implantable heart. Although development of the ventricular assist device is far from complete, prototype models are already being tested in pa-

² Material about the artificial heart, which is being developed under the aegis of the NIH, is drawn largely from the report of a panel convened by NIH to assess its social implications (142). Since that report does not contain answers to all of the questions that might be asked of a new technology, several of the questions in the present list are left unanswered. A brief description of the purpose, history, and developmental status of the artificial heart is contained in ch. 11, Case 9.

tients. Improvements in biomaterials and energy sources will be necessary before a clinically useful totally implantable artificial heart can be made. Research in these areas is underway.

- . How soon can development and adoption of the new technology be expected if there are no interventions in the normal processes of research, development, testing, marketing, diffusion, and use?

Development of an artificial heart that would be suitable for clinical trials in human subjects is not anticipated in the near future. A prototype device might, however, be available within a decade.

- . How effective is the procedure? Has its medical efficacy been assessed yet? How will medical efficacy be assessed? Are rigorously controlled clinical trials possible? Underway? If controlled trials are not possible for technical or ethical reasons, is there, any other way to insure that the technology is medically effective?

Because a clinically useful device has not yet been developed, no estimates of efficacy can be made. When a totally implantable artificial heart is available, controlled trials will be possible. However, it may be difficult to resist pressures from desperate patients and their families for implantation of an incompletely tested artificial heart. The artificial heart might be tested on patients facing imminent death.

- . What are the potential or proven dangers of the technology to individuals using it?

For some time after its introduction, the artificial heart will be experimental, and those accepting it will face the possibility of complications and even death. If the device is nuclear powered, the individual may also face dangers from radiation exposure.

WHAT ARE THE IMPLICATIONS OF THE TECHNOLOGY FOR THE PATIENT?

- . What will be the quality of life of the patient who has been treated? Normally active? Moderately restricted? Physically crippled?

A recipient of an artificial heart could reasonably expect to lead an active, productive, fairly normal life.

- . What psychological effects can be anticipated? Guilt? (Because of high financial and social costs to family, etc.) Anxiety? Feelings of dehumanization? Dependency?

Anxieties and even psychoses might be precipitated in heart recipients who are preoccupied by dependence on an inorganic source of power. Such reactions have been observed in patients receiving dialysis for chronic kidney disease. Furthermore, some of the drugs that might be used as supportive therapy e.g., steroids—themselves have psychotropic effects.

- . Will regimentation result from use of the technology? Loss of freedom over one's body?

If nuclear-powered artificial hearts are used, it may be necessary to identify or even monitor movement of recipients in order to protect the nuclear fuel and to recover it after death. Recipients might be required to waive some of the individual freedom most of us take for granted.

- . Will use of the technology increase the probability of a lingering and painful death?

Death from heart disease is sometimes+ although not always-swift and painless. Although the benefits of prolonging life with an artificial heart are obvious, the recipient will have to be made aware of the possibility of death from failure of the implant procedure.

- . Will the effects of the new technology be reversible if the patient feels that its benefits are outweighed by its drawbacks? Will the individual be able to choose to die?

Once surgery is complete, the procedure can be reversed only by removing or deactivating the artificial heart, thereby allowing the patient to die.

WHAT ARE THE IMPLICATIONS FOR THE PATIENT'S FAMILY?

- . What will be the costs to the family? How will the new technology affect family structure?

Implantation of an artificial heart will permit survival of the patient, and the benefits to the rest of the family will be numerous. On the other hand, unless the cost of implantation of the heart is covered by some third-party payer, the enormous financial burdens could impoverish the patient's entire family and strain intrafamily relationships.

- . Will there be any physical dangers to the immediate family?

The plutonium contained in a nuclear-powered artificial heart may, however well shielded, emit radiation that could pose some danger to family members who are frequently close to the patient.

- . Will the device or procedure be psychologically acceptable to the family?
- . Will active cooperation or assistance of family members be necessary on a continuing basis?
- . How 'will the new technology affect individual or family budgets? What purchases will families forego if they have to pay for the new technology?

WHAT ARE THE IMPLICATIONS FOR SOCIETY?

- . Will the new technology change the demographic characteristics of the society? For example, can changes in sex ratios or age distribution in the population be anticipated ?

Many candidates for heart implantation will be elderly; if the procedure is effective, the percentage of elderly in the population will increase. Also, because women are less prone to heart disease than men, effective implants may increase the ratio of men in the elderly part of the population. However, because candidates for this technology make up only a small fraction of the population, the impact will be minimal.

- . Will the new technology affect reproductive capability of patients and thus change the genetic pool and the prevalence of genetic diseases?

Some cardiac disease is of genetic origin. If the artificial heart allows carriers to reproduce when they otherwise would not, then there will be an effect on the population's gene pool: the artificial heart would generate new candidates for its future use. On the other hand, if coronary disease of genetic origin does not cause symptoms until carriers are past child-bearing age, then use of the artificial heart will not affect the gene pool. In any case, the effect would be quite small.

- Will existing social value systems affect development, acceptance, and use of the technology ?

When the lives of specific, identifiable persons are in jeopardy, our society is inclined to try to preserve these lives at any cost. Society seems to emphasize development of therapeutic technology over related priorities such as disease prevention. Therefore, work on the artificial heart will probably receive continued support, and a clinically useful device will be accepted rapidly and may be paid for by Federal health care programs. In fact, a special program, such as the one for renal dialysis (see Case 5 in chapter II), may be created to provide reimbursement for heart implants.

- What kinds of people presently get help from existing alternatives to the proposed technology? Who will be eligible for help from the new technology? How will patients be selected for the procedure?

If the artificial heart works well, the demand for it maybe so great that society will find it difficult to supply the device to all who want it. Even assuming an adequate supply, society may be unwilling to supply the device at public expense to all needful patients. Convicted criminals, drug addicts, and other persons viewed as noncontributing members of society may be excluded. Any process of rationing life on the basis of social worth would have a major impact on public values.

- . Will use of the new technology by an *individual* create threats to the *environment* that are properly the concern of the entire society?

If nuclear-powered artificial hearts are used, there will be a finite danger of radiation damage from the plutonium carried by mobile recipients. Particularly troublesome is the remote possibility of accidental rupture of the shielding material.

- Will introduction of the new technology challenge important beliefs and values of the society about birth, gender, bodily integrity, personal identity, marriage and procreation, respect for life, right to live, right to die, responsibility for each

other? Will introduction of the new technology result in changes in these values?

The artificial heart will raise questions about the nature of death. Thus, even if a patient showed no other signs of life, stoppage of the artificial heart seem of greater moment than turning off a respirator. For patients in whom the artificial heart merely prolongs misery, it may be necessary to develop a concept of a "right to die."

- Will knowledge be gained from implementing the new technology that will be useful for society? Will the technology be useful for nonmedical purposes?
- Will the public demand knowledge about or dissemination of the new technology? Can the public be educated to the implications of the technology? What role does the general community have in decisionmaking? Will the effects of the technology be easy to monitor?
- Will the technology alter any basic institutions of society (e.g., schools, recreational facilities, prisons) ?

WHAT ARE THE IMPLICATIONS FOR THE MEDICAL-CARE SYSTEM?

- What alternative, available technologies would the proposed innovation replace? Would it be used in conjunction with or instead of available technology? Are there other proposed but still undeveloped technologies that would solve the same problem?

There is presently no effective treatment for those with inadequately functioning hearts. The artificial heart will replace less satisfactory treatments such as heart transplantation. More effective preventive or therapeutic interventions might be developed from research, but they are unlikely to be immediately helpful to the group that would benefit from the artificial heart—the group with far-advanced disease.

- What will the impact of this technology be on the demand for and effectiveness of other procedures or services? Preparatory and followup resource needs? Other medical and psychosocial supports?

Implantation of an artificial heart is a surgical procedure that requires sophisticated hardware. To insure the success of the procedure, however, intensive use of a variety of other technologies will be required. These include intensive-care units, pharmaceuticals, and follow-up social and psychological counseling.

- How will the proposed innovation affect future programs aimed at the development and use of other new technologies?

Availability of an effective artificial heart will increase incentives for developing screening, diagnosis, and emergency care programs and facilities, so that potential recipients could be found and then kept alive until the time of surgery. Also, success of the program may encourage other goal-directed, technology-intensive solutions to major health problems-and their impacts will eventually have to be considered.

- Will the new technology strain existing resources? Given limited resources for the present system of medical-care delivery, which (if any) medical services would have to curtailed to provide funds and manpower for the new technology? Who will decide among competing priorities?

The total cost of each artificial heart implantation is estimated at \$15,000 to \$25,000, although costs might be reduced later if large numbers of devices were used. However, risks of complications, changes in support services, and so forth, could add substantially to costs. Much of the cost would presently be covered by medical insurance, but existing patterns of coverage would make the device more available to upper than lower income groups.

- If the technology is in short supply and selection of patients is necessary, will the choice be left to the physician? Who will determine the criteria for selection?

The device will probably be in short supply, especially in the early phases of testing and diffusion. At these early stages, eligibility for implantation will probably be determined by research clinicians. It will be up to them to develop mechanisms for patient selection and to decide whether medical status and/or "social worth" should be used as criteria.

- What will be the effects of the new technology on primary care? Will it cause a change in the ratio of family practitioners to specialists? Foster specialization? Increase professional power? Promote a technological elite? Depersonalize the relationship between doctor and patient? Enhance or challenge the trust of patients in their doctors?

The artificial heart would be a major new development in the trend toward high-technology medicine, with all that this trend implies for specialization, depersonalization, and the delivery of care by teams located in very large medical centers. This trend conflicts with current efforts to utilize family practitioners to provide better ambulatory care with emphasis on prevention.

- Will the new technology affect the values of health professionals?

Physician behavior is now largely guided by the precept that one must do whatever is possible for the individual patient. As physicians see enormous sums spent on heart implants at the expense of preventive or therapeutic programs that would benefit many, they may begin to question this dogma.

- If the new technology proves effective, will there be pressure for widespread use? Who will apply pressure: patients, physicians, manufacturers? Would excessive use result in adverse effects? Will designation of the technology as "experimental" curtail use (or overuse) ?

There will undoubtedly be pressure to implant the artificial heart in patients facing imminent death. Judgments will have to be made about how quickly successive human trials should follow successful or unsuccessful experiments, and which, and how many, medical institutions should participate in the experiments.

- Are present standards for the protection of human subjects and informed consent adequate for the case at hand?

The artificial heart raises difficulties because of the likelihood of death without it. The process of obtaining informed consent should include full and candid disclosure of the risks and benefits of implanting the artificial heart. The patient will have to understand that many problems remain the subject of further scientific study.

- Will geographic variations in availability of the new technology be important?

Initially, only a few medical centers may have the personnel and facilities to implant an artificial heart. This may be a good thing, since expensive and wasteful duplication of facilities would be avoided, and since the more frequently a surgical team does a procedure, the better its results are likely to be. However, procedures would have to be developed to insure access of patients to appropriate facilities even if the physical distance between home and the hospital is great.

- Does the technology address a serious deficiency in medical care?
- Will use of the new technology cause changes in manpower needs? Will more or fewer physicians, paraprofessionals, technicians, etc., be required? New administrative personnel or structures? Changes in the institutional or geographical distribution of personnel?
- Will the new technology affect the status of medical personnel? Will it require changes in current practices of licensing or training of practitioners? How will the technology affect the income of health-care providers?
- Will changes in nonmedical systems (e.g., schools) be necessary to insure effective medical use of the new technology?
- Will malpractice insurance rates or regulations be affected?

WHAT ARE THE IMPLICATIONS FOR THE LEGAL AND POLITICAL SYSTEMS?

- Will problems of justice, access, or fairness arise? Will they lead to litigation?

If artificial hearts are initially limited in quantity, life-and-death decisions will have to be made about their allocation. Particularly if the costs of the implant are publicly supported, allocation decisions may be contested in the court system. On the other hand, use of artificial hearts rather than human heart transplants would eliminate the risk of legal proceedings arising out of questions concerning the death of organ donors.

- Will the manufacturer be liable for damages resulting from failure of the technology? Will liability extend only to damage to the individual or will it cover environmental effects as well?

Liability for failure of the device as opposed to surgical failure might fall on the manufacturer, since physicians and hospitals, as well as patients' families, could bring litigation.

- Will the quality (efficacy, safety, etc.) or use of the new technology require legal regulation? Who will formulate the regulations, and how will they be enforced?

In the case of a nuclear-powered artificial heart, new legislation might be needed to insure prompt identification of bearers and postmortem removal of the fuel source. A large staff might be necessary to enforce such regulations.

- . Will use of the new technology require changes of the definitions of death or suicide?

By maintaining circulation and heartbeat independent of other vital functions, the artificial heart would render some ideas about death moot; more reliance would have to be placed on alternate definitions such as "brain death. "

- . Can political pressures for increasing availability be anticipated? What individuals or groups will be likely to be politically active in urging acceleration or deceleration of Government support for the new technology?

As in the case of kidney dialysis (see ch. II), availability of a lifesaving but exceedingly expensive treatment such as heart implantation might trigger pressure for its public funding. The ability and desire of the Government to finance implants would have to be considered. Additionally, such pressure-enactment of a support program—might lead to broader consideration of the financial mechanisms for delivery of health services generally.

- . Will patients have the legal right to accept or refuse treatment? Will new regulations be required to insure voluntary, informed consent?

WHAT ARE THE IMPLICATIONS FOR THE ECONOMIC SYSTEM?

- . What is the projected or present overall monetary cost of adopting the new technology? Can cost reductions or increases be anticipated in the future?

If the totally implantable artificial heart were available today, the direct costs of its use would be at least \$500 million per year (based on an estimate of 20,000 eligible patients per year). This figure does not include a number of indirect costs that have yet to be properly calculated.

- . What are the economic implications for the medical-care system? Will overall costs be increased or decreased? Will additional personnel or large capital expenditures be required to support the technology?

Overall medical costs will be increased; large capital expenditures and additional personnel will be required to support medical facilities capable of carrying out heart implants.

- . How do costs of the new technology compare with costs of potential substitutes?

Alternative treatments are unsatisfactory for the group in question.

- . Will income maintenance be required for those using the technology? What are the implications for programs of disability or life insurance? Pension funds? The Social Security System ?

Artificial heart recipients of young or middle age will be able to return to work and support themselves. However, an expanded population of the

elderly, kept alive by implanted hearts, might strain the resources of pension funds or the Social Security System.

- Who will pay? Who can be expected to pay? Will Government support be required for development and/or use of the new technology?

Without Government support, development will be slowed and clinical use will probably be limited.

- What market forces will promote or retard development and use of the new technology?
- Will nonmedical sectors of the economy be affected? (E.g., will changes in diet affect food consumption?)
- How will the technology affect the national economy? Will development and use produce jobs? Who will pay for development? How will this affect overall productivity? Will the tax structure and rates be affected?
- If large-scale Government support is requested, with what national priorities will the new technology compete? What Government programs might suffer if funds are diverted to the new technology?

Although many of the questions in this list are relevant to the case of the artificial heart, no single medical technology can be expected to exemplify all impact areas. The importance of some of the questions that are not applicable to the artificial heart can be dramatically illustrated by material drawn from other cases.

For example:

CHOOSING THE SEX OF CHILDREN

- Would the technology have any effects on the demographic structure of the population?

It is already possible to determine the sex of a child in the uterus, and to carry out an abortion if it is not of the sex desired. Within the next few years, methods for predetermining the sex of children may become available. Use of these new techniques could have important impacts on such demographic characteristics as the ratio of male to female births, average family size, overall birth rate, and the sex composition of families.

PSYCHOSURGERY

- Does the technology affect the patient's right to give informed consent?

Psychosurgery raises important ethical questions about informed consent. Some investigators believe that violent behavior is related to physical brain dysfunction, which can be controlled by destruction of parts of the brain. The effects of this procedure are open to serious question, and the long-term implications of psychosurgery are not understood. However, the incidence of

psychosurgery may increase in the years ahead because of increasing public concern about violence and disillusionment with other forms of therapy. Two questions about informed consent arise. First, if candidates for psychosurgery are chosen because they are judged to be irrational, might "informed consent" be given little weight? Second, a prison system might offer reduced sentences or outright freedom to those willing to submit to psychosurgery. Would these circumstances constitute inherent coercion?

- Is the procedure reversible?

A procedure making destructive lesions in the brain is not reversible—a piece of the brain cannot be replaced, and no form of prosthetic device is available. If undesired effects result from the surgery, there would be no way to reverse them. Possible ill effects would include mental dullness, epilepsy, and personality changes.

Thus, specific questions will be more or less important, depending on the technology that is being considered. Furthermore, it may be necessary to pose the questions in different ways in order to elicit important information about different types of medical technology. As discussed in chapter II, technologies are used for different purposes such as the prevention, diagnosis, and treatment of disease. The implantable artificial heart, used above to illustrate a variety of social impacts, is aimed at treating disease. In examining a diagnostic technology, one would have to consider the therapeutic measures that would be available once disease was diagnosed, and the impacts of using those treatments.

The questions presented above illustrate the broad range of social impacts that might accompany introduction of a new medical technology. The next chapter describes how the methods of technology assessment can be used to ask these questions, in a formal and systematic way, of developing medical technologies.