

Although the current situation with the artificial heart represents a great responsibility, it also presents an opportunity. Whereas advances such as the computed tomography scanner were introduced by private industry and could not be effectively influenced by post hoc regulation, the introduction and distribution of circulatory device technology could be carefully controlled by the Government on its own terms. We strongly believe that the time for discussing this matter is now. At this point, a clinically effective artificial heart is still many years away. From the perspective of a member of society, investment in artificial heart devices may contribute no more to saving his or her life and health than would a comprehensive, effective cardiac disease prevention program. This fact gives us considerable leeway in how we prefer to attack the massive costs of heart disease in our society.

Calabresi and Bobbitt, in their book *Tragic Choices* (13), introduce the concept of first and second order decisions in the development and allocation of lifesaving technologies. The first order decision for the artificial heart is the decision about whether or not to proceed with its development. The second order decisions are who should receive the device and who will pay for it. As Calabresi and Bobbitt point out, it is easier to stop or change direction at the first order decision level than at the second.

The point at which Federal Government intervention is most likely to have a real leverage is at the first order decision level—whether to continue to fund the research that might make the artificial heart a clinical reality. If a breakthrough were to occur that made a clinically acceptable device a reality, or even a strong possibility, it is likely that the demand of heart patients, their families, and physicians for this potentially life-extending treatment would overwhelm even carefully constructed regulatory

and financial checks on device diffusion. The dialysis case is instructive here—nobody wants to be put in the position of saying we will not save identifiable lives because a procedure is too expensive. Consideration of regulatory and reimbursement issues is important, both because it may be effective to some limited degree in making the diffusion of the artificial heart more rational and orderly and because it will heighten awareness of the magnitude of the potential impact of an artificial heart on the health care system.

In an era of limited resources, it is imperative that such a potentially expensive innovation as the artificial heart be carefully compared with other social and medical programs designed to extend life and improve its quality. Such a comparison will require a full and candid understanding of the likely costs and benefits of the device. We have found that before a complete understanding of the impact of an artificial heart may be achieved, two very important questions must be resolved. First, the Government must decide whether it is willing and has the capability to ensure equitable access to the device—assuming this responsibility may substantially increase the perceived cost of the program. Second, the acceptance or rejection of a nuclear power source should be made explicit—the nuclear heart device may substantially enhance the attractiveness of the device from a clinical standpoint, but will also involve substantial social costs and risks. These two decisions will have a marked influence on the balance of costs and benefits of the device, and they should be fully debated and resolved before a final commitment to artificial heart development is reached. Insofar as we may be faced with a \$1 billion to \$3 billion annual commitment in the future, the time to make these decisions is now.

SUMMARY

Research to develop a permanently implantable artificial heart that could be used to replace a failing natural heart has been funded by NHLBI

since 1964. At the program's inception, there was considerable optimism that the successful development of such a device would provide a

means of treating serious cardiac disease by 1970—well before biomedical advances were expected to produce effective preventive treatment. But now, more than 15 years later, a totally implantable artificial heart is still a distant goal. This case study has reviewed the potential benefits, costs, and risks of continued investment in this medical innovation, as well as the technological problems that remain to be solved.

Cardiac disease kills over 800,000 persons yearly. The number of people that might benefit from total heart replacement depends on the severity of concomitant illness, age restrictions, access to emergency coronary care, and the nature of the device itself. Our estimate of a pool of 33,600 candidates yearly assumes that a prospective candidate's death is imminent, that circulation can be supported long enough for transportation to an institution with appropriate facilities, that the patient does not suffer from serious or chronic noncardiac disease, and that he or she is under 65 years of age. A lower estimate of 16,000 candidates is defined on the likelihood of inadequate mobile coronary care and surgical facilities, at least initially, in some parts of the country. If the device is highly successful, we estimate that there might be as many as 66,000 candidates annually.

If the artificial heart is perfected, it will have a substantial impact on those who suffer from cardiac disease now or in the future. We estimate that the availability of the artificial heart may extend the lives of such individuals, on the average, by 0.6 of a year (about 210 days). It might extend the lives of randomly chosen 25-year-old members of the population, on the average, by about 0.0966 of a year (about 35 days). An optimistic estimate is that 60 percent of artificial heart recipients employed prior to implantation may return to work. The experience of patients undergoing CABG surgery suggests that as few as 50 percent of persons aged 55 to 65 years would return to work; the experience of heart transplant patients suggests that the lower limit might be 20 percent. The range of estimates varies with the reliability of the device and the adequacy of rehabilitative care.

As the technology becomes available, it will be nearly impossible to deny the demand for its widespread use, as the recent history of hemodialysis demonstrates. Even the minimum estimates of the cost for an individual to receive an artificial heart involve an amount that would be a severe burden on most families. Our estimates for the cost of manufacturing and surgically implanting an electrically powered device (not including previous development costs) range from \$24,000 to \$75,000 per patient; these are initial costs. Continuing medical and technological care could range from \$1,800 to \$8,800 per patient per year. Insurance companies will probably be unwilling to cover the high costs of this treatment without special premiums or other incentives. Thus, the Federal Government will be faced with a serious dilemma—to allow those who cannot afford to pay privately to do without a lifesaving device, or, alternatively, to devote up to an additional \$1 billion to \$3 billion annually to this new medical technology. Such a commitment is so great as to dwarf all of the funds spent to date on the development of the artificial heart and other circulatory-assist devices.

A decision to finance artificial heart implantation with Federal funds must not be taken lightly. It involves additional costs and planning for adequate facilities, training of personnel, and a strong program to rehabilitate patients who must deal with the inconvenience and anxiety related to daily recharging of batteries, potential mechanical or electrical failure, and total reliance on an implanted machine. Cost considerations must also take into account potential loss of other social programs displaced by the development of the artificial heart. The artificial heart may proportionately raise social expenditures financed through medicare and social security that will have to come from other social programs. Funds that support the training of heart surgeons and technicians for a large-scale implantation program may deter the urgency with which research on cardiac disease prevention or alternative treatments is pursued. Recent work in cardiac disease prevention at Stanford University (27) and in Finland (60) indicates that

an effective prevention program definitely reduces the risk factors associated with CHD and may have a greater potential to reduce death from cardiac disease.

While artificial heart research has led to useful therapeutic inventions and substantial advances in understanding, the development of a clinically acceptable artificial heart seems unlikely to be realized in the near future. As yet, neither a hemocompatible material nor a portable power source that can meet the specifications for a long-term, implantable heart in laboratory testing has been developed. Current prototypes of 2- and 5-year LVADs use electrical battery systems that still have mechanical and operational liabilities. In clinical trials projected for the mid-1980's, these devices will provide an experimental model to assess the reliability of the engine under conditions of extended use, as well as the quality of life that might be expected from an artificial heart. Production and implantation will also result in a more accurate picture of total economic costs of the device and surgical procedure.

In addition to investment in battery-powered devices, several million dollars of DOE funding (primarily through the Energy Research and Development Agency) have been devoted to research on a nuclear power source. Should we arrive on the brink of a successful device that lacks only an acceptable power source, it may be difficult to resist the pressure to go ahead with a Pu-238 powered engine. The costs and risks of such a device are enormous. Because of its dangerous qualities and its value (\$1,000 per g for a device using 50 g of Pu-238), the material would have to be closely guarded from manufacture, through transportation and storage, to implantation, until removal upon the death. Strict safeguards would have to be imposed on recipients to protect them from health risks due to radiation, physical injury, or kidnapping. In light of these considerations, we believe it is important that a firm commitment against the use of nuclear-powered devices be made so that the ultimate potential for a safe and acceptable heart device may be evaluated.

The current situation with the artificial heart represents a great responsibility, but also represents an opportunity to control with care the introduction of circulatory device technology. At this time, a clinically effective artificial heart is still many years away. From the perspective of a member of society, investment in artificial heart devices may be no closer to saving his or her life and health than a comprehensive, effective cardiac disease prevention program. This fact gives us considerable leeway in how we prefer to attack the massive costs of heart disease in our society. For this reason, we should compare the benefits and costs of the artificial heart in competition with other social and medical programs designed to extend life and improve its quality. We must first decide whether to proceed with development of the artificial heart, knowing that it will require a large commitment of resources. If we assume this commitment, we must then consider issues of who should receive the device, who will absorb the costs of manufacture and implantation, and most importantly, what opportunities will be lost through an inability to fund other social programs.

In sum, we believe that two major issues involving the development of the artificial heart must be resolved in order to comprehend fully the device's total impact. First, the Federal Government must decide whether it is willing and has the capability to ensure equitable access to the device—assuming this responsibility may substantially increase the perceived cost of the program. Second, the acceptance or rejection of a nuclear power source should be made explicit—the nuclear heart device may substantially enhance the attractiveness of the device from a clinical standpoint, but will also involve very large social costs and risks. Because these two decisions will have a marked influence on the balance of costs and benefits of the device, they should be fully debated and resolved before a final commitment to artificial heart development is made.