aim for future cost comparisons of these two approaches would be to collect information in a central registry over the next decade on the results of clinical trials of the LVADs and on the outcomes of prevention programs.

POLICY RECOMMENDATIONS

Artificial heart research represents the first prototype of a comprehensive Federal Government program to develop a concrete medical device. As such, its significance extends beyond the pure success or failure of the research to include the lessons that affect future Federal commitment in applied health technology. In the following discussion, we address three areas of public policy raised by artificial heart development: 1) program administration, 2) regulation, and 3) reimbursement and distribution.

Program Administration

The Federal circulatory-assist devices program has led to useful therapeutic inventions (such as the intra-aortic balloon and temporary LVADs), yet the development of a clinically effective artificial heart appears to be decades in the future. The manner in which research priorities are established is of fundamental importance for the artificial heart and alternative forms of treatment.

Previous allocation decisions led to a research strategy in which many identical contracts were assigned in order to hasten the proliferation of technological options, rather than the usual system of investigator-initiated grants. Some consultants expressed the opinion that this approach resulted in unnecessary duplication of research effort, that it discouraged many talented researchers from becoming involved, and that the resulting competition interfered with the full exchange of scientific information, thus compounding the magnitude of the biomaterials and energy source problems discussed earlier. The relative lack of dissemination of information may have substantially slowed the program's progress.

NHLBI has moved to correct these shortcomings through annual meetings of contractors and a larger emphasis on grants. A greater dialog between Federal program administrators and researchers should be encouraged early in any research program to ensure widespread consensus about the appropriate level, distribution, and direction of research effort. If a mission-oriented approach is deemed appropriate, it will be necessary to have a careful evaluation of the knowledge base that is necessary to identify areas of study that may require further basic research. An adversarial proceeding that focuses organized "skepticism" on the potential for success may best uncover such areas.

The major responsibility for the evaluation of the program rests entirely with the community of surgeons, engineers, and administrators who are directly involved in the research. In the early years, this led to an emphasis on technological issues and little consideration of the larger societal needs and projected impact of the device. We certainly acknowledge the attempts by NHLBI to assess a broader range of outside opinion through the 1969 Ad Hoc Task Force on Cardiac Replacement (2) and the 1973 Artificial Heart Assessment Panel (51). However, these bodies were charged only with advising NHLBI on internal policy in areas limited by their charges, and they had no authority to evaluate alternative research strategies and weigh relative priorities for the allocation of public funds.

It appears that the most comprehensive evaluation of the costs and benefits of artificial heart research came from the Artificial Heart Assessment Panel (51), which did not stand to benefit directly from the program in question. That panel was the first to examine in depth the costs to society of using a nuclear power source. The panel's recommendation that nuclear engine development be reemphasized led to the cessation of nuclear research by NHLBI. In the case of the nuclear-powered artificial heart, taxpayers might have recognized savings from an inde-

pendent, broad-based analysis earlier in the program, and the electrical systems under research might be considerably more advanced today.

Given the central role of such analyses in decisionmaking, it appears desirable to establish an independent agency to consider the costs and benefits—including the manifold social and economic implications—of medical innovations. To ensure that potential societal impacts are considered early in the research process, analysis of the costs and benefits of medical innovations might take place before the initial allocation of funds by Congress. In rapidly changing areas of biomedical understanding, independent analysis should also be undertaken at intervals during the life of a program to avoid ongoing expenditures when more viable alternative approaches exist. The National Center for Health Care Technology (NCHCT) was established in 1978 to anticipate and evaluate the impact of health technologies and it represented a constructive step toward such an independent authority. However, its responsibilities now belong to a study section of the National Center for Health Services Research (NCHSR), since NCHCT's appropriations were not renewed in 1982.

Regulation

The greatest Federal control over biomedical innovation is currently through regulating the introduction of new innovations through comprehensive legislation covering drugs and medical devices. A way to ensure that better information is available for making these regulatory decisions is discussed below.

The process of developing a new medical technology involves several types of testing—animal studies, clinical trials, and experimental clinical use. Considerable controversy surrounded the decision to use the 2-week LVAD in clinical trials of patients unable to resume cardiac function after open-heart surgery in 1975. Completed LVAD implants in animals had been successful, but, as is true with most experiments in animals, the results could not readily be translated to the clinical situation. At least one major NHLBI contractor participated in the decision to begin the clinical trials, raising serious questions about conflict of interest.

Ultimately, clinical trials of 2- and 5-year versions of the LVAD are planned. Since each of these longer term devices confronts the major problems of the total artificial heart—energy supply, actuator and engine design, durable and hemocompatible materials—their testing can provide an experimental model to assess the reliability, economic costs, and quality of life expected from a total artificial heart. Before clinical trials with these LVADs begin, adequate information on all LVADs under research should be collected in order to select the best model for testing. When clinical trials do take place, the review process should set criteria and boundaries to confirm their safety and ensure the protection of human subjects. It is especially important that local institutional review boards be fully involved in decisionmaking (i.e., that they not be bypassed on the grounds that the device constitutes "emergency therapy"). The larger implications of such criteria might constructively be addressed by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

The Food and Drug Administration (FDA) was recently given authority by Congress through the Medical Device Amendments to develop and enforce standards for the performance, efficacy, and safety of all medical devices. No regulations have yet been written for the LVAD or for the artificial heart. We recommend that when FDA does develop regulations, it coordinate efforts with NIH to develop a central repository of all (private and NIH) data on LVAD/artificial heart development, performance, and clinical results. In addition to data on technical and protocol details, information should be collected on patient status (i.e., socioeconomic status, age, race, sex) and details of informed consent measures. Submitting this information should be mandatory for all involved in order to establish a knowledge base, and monitoring should take place to maintain quality control and compliance. This information should be used in determining criteria or regulations for

commercial marketing and device distribution, as well as R&D.

The 1973 report of the Artificial Heart Assessment Panel (51) called into question the active search for a nuclear-powered artificial heart. The panel expressed concern about the dangers of walking-plutonium proliferation and of exposure of the patient and relatives to higher than acceptable levels of radiation. While suggesting that development might proceed pending more complete evidence of risk, the panel specifically recommended against any experimental implantation in humans.

The potential costs of a nuclear-powered device may be very great. Aside from the health risks to the individual, the strict safeguards necessary to avoid theft or loss of plutonium may well involve an unacceptable threat to the quality of life of the recipient and raise many thorny issues of civil liberties. However, there remains to date no clear regulatory policy fully excluding the possibility that a nuclear device might be implemented in the future.

Meanwhile, the development of a clinically acceptable energy alternative is progressing slowly. The question arises, therefore, whether research on the artificial heart is progressing with the conscious or unconscious assumption that a nuclear power source is still a viable alternative. Should we arrive on the brink of a successful device that lacks only an efficient power source, it would be difficult to resist the pressure to go ahead with a nuclear engine. For this reason, we believe it is important that a firm commitment against the use of nuclear-powered devices be reached.

Reimbursement and Distribution

As noted earlier in this case study, the cost to an individual for artificial heart implantation and continuing care will be very great. These expenses will place access of the device out of the hands of many needy patients, unless a plan for socializing these costs is formulated. In the early stages of availability, insurance companies might well be expected not to assume the large costs.

The prevailing trend already shows the Government assuming responsibility for ensuring equitable access to expensive medical technologies even for those technologies initially developed without direct Government intervention (e.g., the artificial kidney). When the Federal Government underwrites the majority of research for an innovation, as it has with the artificial heart, the issue of access assumes greater significance. In our opinion, in such an instance, the responsibility for ensuring equitable distribution rests clearly on the Government. The 1973 Artificial Heart Assessment Panel noted (51):

> Particularly in view of the substantial commitment of public funds for development of the artificial heart, implantation should be broadly available, and availability should not be limited only to those able to pay. This objective can be accomplished through either private or government insurance mechanisms.

At the same time, a decision by the Federal Government to assume this responsibility must not be taken lightly. A decision to finance implantation federally may well commit the Government to an annual outflow of several billion dollars for a single therapeutic modality that will have relatively little impact on national life expectancy. 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. This commitment also implies planning and additional costs to ensure an adequate inventory, facilities, and personnel for implantation, continuing medical care, and rehabilitation. The specific details of any cost-sharing program will obviously affect the speed and extent of clinical application. If there is no incentive to centralize resources or to encourage efficient use, the costs of application will rise as the procedure diffuses throughout the country. The absence of cost-containment incentives may also result in a relaxation of medical criteria to provide artificial hearts to patients not faced with imminent death from cardiac disease.