The Artificial Heart: Costs, Risks, and Benefits

May 1982

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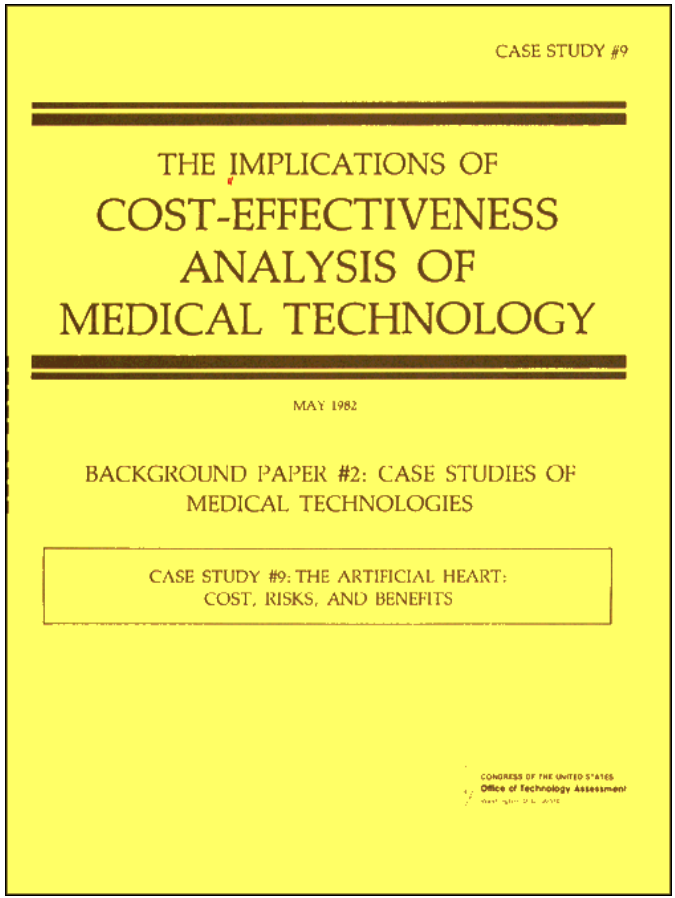

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THE IMPLICATIONS OF COST-EFFECTIVENESS ANALYSIS OF MEDICAL TECHNOLOGY

MAY 1982

BACKGROUND PAPER #2: CASE STUDIES OF MEDICAL TECHNOLOGIES

CASE STUDY #9: THE ARTIFICIAL HEART: COST, RISKS, AND BENEFITS

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OTA Background Papers are documents containing information that supplements formal OTA assessments or is an outcome of internal exploratory planning and evaluation. The material is usually not of immediate policy interest such as is contained in an OTA Report or Technical Memorandum, nor does it present options for Congress to consider.

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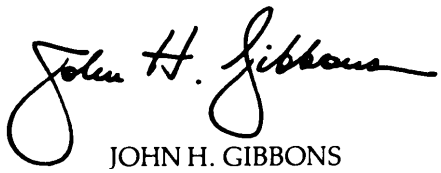
Foreword

This case study is one of 17 studies comprising Background Paper #2 for OTA'S assessment, *The Implications of Cost-Effectiveness Analysis of Medical Technology.* That assessment analyzes the feasibility, implications, and value of using cost-effectiveness and cost-benefit analysis (CEA/CBA) in health care decisionmaking. The major, policy-oriented report of the assessment was published in August 1980. In addition to Background Paper #2, there are four other background papers being published in conjunction with the assessment: 1) a document which addresses methodological issues and reviews the CEA/CBA literature, published in September 1980; 2) a case study of the efficacy and cost-effectiveness of psychotherapy, published in October 1980; 3) a case study of four common diagnostic X-ray procedures, published in April 1982; and 4) a review of international experience in managing medical technology, published in October 1980. Another related report was published in September 1979: *A Review of Selected Federal Vaccine and Immunization Policies.*

The case studies in *Background Paper* #2: *Case Studies of Medical Technologies* are being published individually. They were commissioned by OTA both to provide information on the specific technologies and to gain lessons that could be applied to the broader policy aspects of the use of CEA/CBA. Several of the studies were specifically requested by the Senate Committee on Finance.

Drafts of each case study were reviewed by OTA staff; by members of the advisory panel to the overall assessment, chaired by Dr. John Hogness; by members of the Health Program Advisory Committee, chaired by Dr. Frederick Robbins; and by numerous other experts in clinical medicine, health policy, Government, and economics. We are grateful for their assistance. However, responsibility for the case studies remains with the authors.



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Preface

This case study is one of 17 that comprise Background Paper #2 to the OTA project on the Implications of Cost-Effectiveness Anlalysis of Medical Technology * The overall project was requested by the Senate Committee on Labor and Human Resources. In all, 19 case studies of technological applications were commissioned as part of that project. Three of the 19 were specifically requested by the Senate Committee on Finance: psychotherapy, which was issued separately as background Paper #3; diagnostic X-ray, issued as Background Paper #5; and respiratory therapies. The other 16 case studies were selected by OTA staff.

In order to select those 16 case studies, OTA, in consultation with the advisor-y panel to the overall project, developed a set of selection criteria. Those criteria were designed to ensure that as a group the case studies would provide:

- examples of types of technologies by function (preventive, diagnostic, therapeutic, and rehabilitative);
- examples of types of technologies by physical nature (drugs, devices, and procedures);
- examples of technologies i n different stages of development and diffusion (new, emerging, and established);
- examples from different areas of medicine (such as general medical practice, pediatrics, radiology, and surgery);
- examples addressing medical problems that are important because of their high frequency or significant impacts (such as cost) ;
- examples of technologies with associatecl high costs either because of high volume (for low-cost technologies) or high individual costs ;
- examples that could provide informative material relating to the broader policy and methtodological issues of cost-effectiveness or cost-benefit analysis (CEA / CBA); and
- examples with sufficient evaluable litera - ture.

On the basis of these criteria and recommendations by panel members and other experts, OTA staff selected the other case studies. These 16 plus the respiratory therapy case study requested by the Finance Committee make up the 17 studies in this background paper.

All case studies were commissioned by OTA and performed under contract by experts in academia. They are authored studies. OTA subjected each case study to an extensive review process. Initial drafts of cases were reviewed by OTA staff and by members of the advisory panel to the project. Comments were provided to uthors, along with OTA'S suggestions forrevisions. Subsequent drafts were sent by OTA to numerous experts for review nd comment. Each case was seen by at least 20, ad some by 40 or more, outside reviewers. These reviewers were from relevant Government agencies, professional societies, consumer and public interest groups, medical practice, and academic medicine. Academicians such as economists and decision analysts also reviewed the cases. In all, over 400 separate individuals or organizations reviewed one or more case studies. Although all these reviewers cannot be acknowledged individually, OTA is very grateful for- their com - ments and advice. In addition, the authors of the case studies themselves often sent drafts to reviewers and incorporated their comments.

These case studies are authored works commissioned by OTA. The authors are responsible for the conclusions of their specific case study. These cases are not statements of official OTA position. OTA does not make recommendations or endorse particular technologies. During the various stages of the review and revision process, therefore, OTA encouraged the authors to present balanced information and to recognize divergent points of view. In two cases, OTA decided that in order to more fullv present divergent views on particular technologies a commentary should be added to the case study. Thus, following the case

*Office of Technology Assessment, U.S. Congress, *The Implications of Cost Effectiveness Analysis of Medical Technology*. GPO stock No. 052-003-00765-7 (Washington, D.C.: U.S. Government Printing Office, August 1980).

studies on gastrointestinal endoscopy and on the Keyes technique for periodontal disease, commentaries from experts in the appropriate health care specialty have been included, followed by responses from the authors.

The case studies were selected and designed to fulfill two functions. The first, and primary, purpose was to provide OTA with specific information that could be used in formulating general conclusions regarding the feasibility and implications of applying CEA/CBA in health care. By examining the 19 cases as a group and looking for common problems or strengths in the techniques of CEA/CBA, OTA was able to better analyze the potential contribution that these techniques might make to the management of medical technologies and health care costs and quality. The second function of the cases was to provide useful information on the specific technologies covered. However, this was not the major intent of the cases, and they should not be regarded as complete and definitive studies of the individual technologies. In many instances, the case studies do represent excellent reviews of the literature pertaining to the specific technologies and as such can stand on their own as a useful contribution to the field. In general, though, the design and the funding levels of these case studies were such that they should be read primarily in the context of the overall OTA project on CEA/CBA in health care.

Some of the case studies are formal CEAs or CBAs; most are not. Some are primarily concerned with analysis of costs; others are more concerned with analysis of efficacy or effectiveness. Some, such as the study on end-stage renal disease, examine the role that formal analysis of costs and benefits can play in policy formulation, Others, such as the one on breast cancer surgery, illustrate how influences other than costs can determine the patterns of use of a technology. In other words, each looks at evaluation of the costs and the benefits of medical technologies from a slightly different perspective. The reader is encouraged to read this study in the context of the overall assessment's objectives in order to gain a feeling for the potential role that CEA/ CBA can or cannot play in health care and to better understand the difficulties and complexities involved in applying CEA/CBA to specific medical technologies.

The 17 case studies comprising ***Background Paper #2*** (short titles) and their authors are:

Artificial Heart: Deborah P. Lubeck and John P. Bunker
Automated Multichannel Chemistry Analyzers: Milton C. Weinstein and Laurie A. Pearlman
Bone Marrow Transplants: Stuart O. Schweitzer and C. C. Scalzi
Breast Cancer Surgery: Karen Schachter and Duncan Neuhauser
Cardiac Radionuclide Imaging: William B, Stason and Eric Fortess
Cervical Cancer Screening: Bryan R. Luce
Cimetidine and Peptic Ulcer Disease: Harvey V. Fineberg and Laurie A. Pearlman
Colon Cancer Screening: David M. Eddy
CT Scanning: Judith L. Wagner
Elective Hysterectomy: Carol Korenbrot, Ann B. Flood, Michael Higgins, Noralou Roos, and John P. Bunker
End-Stage Renal Disease: Richard A. Rettig
Gastrointestinal Endoscopy: Jonathan A. Showstack and Steven A, Schroeder
Neonatal Intensive Care: Peter Budetti, Peggy McManus, Nancy Barrand, and Lu Ann Heinen
Nurse Practitioners: Lauren LeRoy and Sharon Solkowitz
Orthopedic Joint Prosthetic Implants: Judith D. Bentkover and Philip G. Drew
Periodontal Disease Interventions: Richard M, Scheffler and Sheldon Rovin
Selected Respiratory Therapies: Richard M. Scheffler and Morgan Delaney

These studies will be available for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Call OTA's Publishing Office (224-8996) for availability and ordering information.

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INTRODUCTION

Current medical technology is often the result of a convergence of clinical research and practice with modern engineering. Advances in electronics, synthetic materials, pharmaceutical development, instrumentation, and computation result in important applications in diagnosis, therapy, and rehabilitation. The artificial heart program is an example of this convergence.

Cardiovascular diseases are still the leading cause of death in the United States. According to the National Center for Health Statistics, heart attacks and strokes—the most lethal and well-known manifestations of cardiovascular disease—claim over 700,000 victims each year. In an effort to prevent some of the deaths, the National Heart Advisory Council in 1963 recommended a long-range program of research to develop a permanently implantable artificial heart that could be used to replace a failing natural heart.

At the time, there was considerable optimism that the successful development of a permanently implantable artificial heart would provide a means of treating serious cardiac disease by **IWO,** well before biomedical advances were expected to produce appropriate preventive treatment (42). The success of cardiac pacemakers, hemodialysis, and prosthetic joint replacement underscored that optimism.

Today, after 15 years and over $180 million in Federal expenditures, * however, a total implantable artificial heart is still a distant goal. This case study, discusses the potential societal benefits, costs, and risks of continued investment in this medical innovation. Many of our estimates and forecasts are hampered by the fact that very little research is directed toward the nature of technical change in medicine and the supply side of medical technology. We hope this case study points to some useful areas of further research on the relationship of public policy to the development of new medical technologies. At a minimum, an assessment of the artificial heart program provides an opportunity to address policy questions concerning the distribution of research funds for treating heart disease, the equitable distribution of medical technology, and the potential costs to society *before* this life-saving technology is available for therapeutic use.

● These Federal expenditures include **$134** million in National Heart, Lung, and Blood Institute (NHLBI) contracts, approximately $30 million in NHLBI grants, and $17 million in Department of Energy (DOE) funding.

HISTORY OF THE ARTIFICIAL HEART

The artificial heart program was created at the National Heart Institute with special congressional approval in 1963. Its ultimate goal is to develop a totally implantable mechanical heart —including an implantable power source— which can be used to replace a failing natural heart. Since 1964, the program has had a succession of organizational names: Artificial Heart/Myocardial Infarction Program, Medical Devices Application Branch (1970), Division of Technological Applications (1972), and Cardiovascular Devices Branch (1973) of the National Heart and Lung Institute. The program is currently administered by the Devices and Technology Branch (1974), of the Division of Heart and Vascular Diseases, of the National Heart, Lung, and Blood Institute (NHLBI).

The effort to construct heart prostheses followed naturally from the successful design of heart-lung pumps that could be used during open-heart surgery to assume (for short periods only) the functions of both the heart and lung. Many medical and technical advances suggested the feasibility of heart replacement: the implantation of artificial heart valves, the development and widespread use of cardiac pacemakers, increasingly successful blood dialysis as a mechanical replacement for kidney function, and the achievement of kidney transplants in humans and heart transplants in animals. The success of the aforementioned surgical techniques demonstrated the possibility of prosthetic replacement, while the immunological rejection and shortage of donors associated with the transplants helped demonstrate the need for a mechanical heart. Other notable technological achievements included the revolution in miniaturized engineering stimulated by the space program, advances in energy technologies (e.g., the plutonium heat engine), and the development of synthetic materials (e.g., teflon and lycra) with outstanding engineering specifications for wear and flexibility (45).

These developments helped set the stage for the construction of prototype hearts by a number of investigators—Adrian Kantrowitz, Michael DeBakey, and Willem Kolff. Much of the earliest work on the artificial heart was carried out, without Federal sponsorship, in academic and research centers.

The search for the *large* capital outlay necessary to finance the initial R&D for the artificial heart was given impetus by nature of the medical and engineering problems that were encountered: finding hemocompatible materials able to withstand continual wear and flexion, finding a power supply, and developing sophisticated miniaturized control systems. The magnitude of these problems discouraged independent development and created a demand for Government involvement.

The artificial heart program was launched in a period of both economic growth and great faith in the powers of science and technology. Heart researchers, such as Michael DeBakey of Baylor University, were enthusiastic about developing an artificial heart and were optimistic that a successful device might take as few as 3 years but no more than 10 years to achieve. By early 1965, there was a 5-year plan for achieving the artificial heart: roughly 1 year to assess the "state of the art," 1 year to design, test, and develop the system, 2 years to develop heart prototypes, and 1 year to test the model and determine standards for mass production (40).

It was widely believed that the approach to the space race (i.e., systems analysis) could be used as a model for organizing technological projects like the artificial heart. A similar approach, including a built-in rivalry among scientists, was therefore adopted by the National Heart Institute. Several researchers worked on parallel development of the separate subsystems of the heart—energy systems, control systems, blood interface materials—that were to be reintegrated into a working device at a later time (33). The decision was also made, based on the success of the space program, to use targeted contracts to private firms to develop parts and materials for the device, rather than the more common research grant procedure (35). This targeted approach, reflecting the specificity of engineering, was based on the assumption that the

basic scientific knowledge necessary to develop a device was available.

In the artificial heart program's early years, rapid growth in resources—from $500,000 in 1964 to $8 million in 1967—nurtured anticipation of early clinical results. Technical difficulties were greater than anticipated, however, and the basic knowledge necessary to design and produce the needed components was not available. There was no solution to two major technical problems: developing hemocompatible biomaterials and a power source. Researchers today are still attempting to perfect an inner surface material for the artificial heart that will not cause adverse chemical reactions when in constant contact with blood, yet is sufficiently durable to flex more than once a second over a decade without cracking or chipping (41,69). A compact, long-lived, and reliable power source has still not been developed; permanently implanted nuclear energy sources, popular in the 1960's, have been given a diminished priority, and greater emphasis is now placed on electrical engines that require a continuous energy supply or recharging.

In 1974, in response to these problems, the artificial heart program was moved into NHLBI's Division of Heart and Vascular Diseases. There it developed a more narrow focus, with an emphasis on the development of circulatory-assist devices that would augment the left ventricle of the heart by pumping blood from the left ventricle to the aorta. In 1975, authorization was given to begin clinical trials of a left-ventricular-assist device (LVAD) to be used temporarily in patients unable to resume cardiac function at the completion of open-heart surgery. Clinical trials for a 2-year implantable LVAD are expected to begin in an estimated 3 to 5 years. Targeted efforts beyond that include the development of a 5-year implantable LVAD and electrically energized engines. Researchers see the longer term implantable LVAD as a significant step, possibly a decade away. *

Parallel work on totally implantable artificial hearts is still continuing. Willem Kolff, at the University of Utah, has a number of calves in which his prototype heart has been successfully implanted. Nevertheless, the power source for a totally implantable artificial heart remains a continuing source of concern. Kolff's calves are on air-driven pumps, tethered to the wall; other prototypes require that an external battery-pack power an implanted motor. Estimates as to when a totally implantable artificial heart system capable of long-term support will be achieved are uncertain. The most common forecast is "many years away." Since the achievement of a totally implantable artificial heart depends on significant advances in basic knowledge and in bioengineering, it remains today a distant goal.

*LVAD research and clinical trials are discussed at greater length in a separate section of this case study.

POOL OF POTENTIAL RECIPIENTS IN THE UNITED STATES

Sources of Candidates

The authors of this case study assume that in order to be a candidate for heart replacement, a person must be in the hospital, with death imminent or highly probable, and must survive for 1 hour after the "replacement" decision is made (i.e., the amount of time needed to set up the operating room and get the patient on cardiopulmonary bypass).

The following three groups are sources of potential candidates:

1. survivors of recent myocardial infarction (heart attack) and/or cardiac arrest with worsening course,
2. persons with worsening chronic severe heart disease, and
3. persons having open-heart surgery whose heart after surgery is unable to reassume the hemodynamic load from the cardiopulmonary bypass pump.

In order to be candidates, persons in the first group would have to survive their attack or cardiac arrest through the following phases: home/

work (attack and replacement decision times), transportation to hospital, treatment in the emergency room, and initial stabilization in the coronary care unit. Candidates in the first and second groups would be primarily patients with ischemic heart disease (IHD), but would also include some patients with rheumatic heart disease (RHD).

The second group would include, in addition, persons with severe cardiomyopathy (heart muscle disease) which has rendered the heart incapable of supporting the body's needs at any level of exertion above absolute rest, and persons with severe electrical instability of the heart which has been refractory to treatment with medication. These individuals, we assume, would have to survive at least 1 hour of hospitalization in order to be candidates.

The third group would consist of persons whose heart is unable to reassume the body's hemodynamic load after the heart has been mechanically bypassed during open-heart surgery. Such surgery includes operations for coronary artery bypass, cardiac valve replacement, and cardiac muscle resection in hearts with severe mechanical or electrical dysfunction.

Our estimates of the number of potential recipients of an artificial heart are presented below. These estimates are based on information available from the Ad Hoc Task Force on Cardiac Replacement in 1969 (1) and recent literature regarding the following:

- the percentage of persons experiencing myocardial infarction or cardiac arrest who die:
  —at home or work,
  —during transportation by mobile coronary units,
  —in emergency rooms, or
  —during stabilization in coronary care units;
- the distribution of "mobile coronary units" (i.e., urban v. rural);
- the total number and distribution of cardiac deaths per year; and
- the prevalence of severe, irreversible, potentially lethal noncardiac diseases in candidates (we assume no change from the 1969 task force estimate of 262/1,000).

We differ from the 1969 task force as follows:

- We do not consider that a patient's prior knowledge of cardiac disease alters the pattern of patient delays in seeking medical assistance, nor that it alters the candidacy status once a patient has been hospitalized.
- We do not concur with the task force's category of "unexpected" deaths, neither with the numerical estimates of such deaths nor with the significance attributed to them. We believe that cardiac deaths can be considered "instantaneous" (occurring in less than 1 to 2 minutes) or "sudden" (occurring in less than 1 hour). The 1969 estimate of 42 percent (98/233) "unexpected" deaths seems unreasonably high for "instantaneous" deaths.

  Further, the 1969 report does not appear to exclude all persons who die within 1 hour after onset of symptoms. As noted earlier, at least 1 hour after the replacement decision is made will be required to prepare the operating room and the patient for heart replacement. We consider that if the patient survives for 1 hour or more in a hospital (avoids "sudden death"), he or she becomes a potential recipient, as reflected in our estimates below.

Finally, we assume that there will be no "elective" replacements, i.e., there will be no implantation in patents who are stable under medical management, regardless of the severity of such patients' disease. This consideration might change over time if the artificial heart proved highly successful.

Estimates of Potential Candidates in the United States, 1979

Group 1: Survivors of Recent Myocardial Infarction and/or Cardiac Arrest

Three separate sets of figures from the medical literature **(23,44,61)** are employed in our analysis of the number of potential candidates

among persons suffering acute myocardial infarction and/or cardiac arrest. Therefore, we present three separate estimates below and then use these to arrive at a pooled estimate.

Estimate A

1. Myocardial infarctions/year.	700,000
less those who survive uneventfully (50%).	–350,000
less those who die before hospitalization (25%)	–175,000
less those die "suddenly" in hospital (s%). . . .	–35,000
Subtotal	140,000
2. Cardiac arrests/year.	300,000
less those who die "at home".	–80,000
less those who die before hospitalization. . . .	–80,000
less those who die in hospital.	–80,000
less survivors (no mechanical damage to heart).	. . –60,000
Subtotal	. . 0
Total estimate A.	140,000

Estimate B

Seventy-five percent of all cardiac deaths are said to occur within 2 hours of symptom onset. Thus, 25 percent of deaths occur after 2 hours; one-sixth of these deaths occur "without warning. "

Cardiac deaths/year.	684,000
less 75% who die within 2 hours.	. –513,000
	171,000
less 1/6 who die "without warning".	. . –28,500
Total estimate B.	142,500

Estimate C

Fifty percent of all cardiac deaths are said to be "immediate" (time undefined). Of the rest, so percent die before hospitalization, and one-sixth die in the hospital "suddenly. "

Cardiac deaths/year.	684,000
less 50% whose deaths are "immediate". .	. –342,000
	342,000
less *5070* who die before hospitalization. .	...171,000
	171,000
less 1/6 who die in hospital "suddenly". . .	. . –28,500
Total estimate C.	142,500

Pooled Estimate

Thus, in group 1 we estimate 140,000 to 142,500 candidates for artificial hearts. The round figure of 140,000 will be used hereafter. *

Group 2: Persons With Worsening Chronic Severe Heart Disease

Patients with severe cardiomyopathy and patients with severe electrical instability of the heart are also prone to die instantaneously or "suddenly." The percentage of those persons who survive 2 or more hours in the hospital, yet have a worsening course, is estimated from figures at Stanford University Medical Center, which serves as a referral center for medical and surgical treatment of patients in both categories. We estimate 11,000 such patients per year.

Group 3: Persons Who Are Unable to Come Off the Cardiopulmonary Bypass Pump Following Open-Heart Surgery

Patients undergoing open-heart surgery occasionally survive the surgery but are "unable to come off the pump, " i.e., the patient's heart will not reassume the hemodynamic load when a transfer is attempted from the artificial cardiopulmonary bypass machinery.

Approximately 100,000 coronary bypass operations are performed yearly, as well as other open-heart surgery. Of the patients undergoing these procedures, we estimate that no more than 1,000 patients a year would be "unable to come off the pump. "

All Groups

By combining the estimates presented above, we estimate the total number of potential candidates for artificial hearts to be 140,000 +

*The figures used in the three estimates presented for this group of potential candidates are compatible with data recently collected in the area of Miami, Fla., which as of 1979 had not yet been published in manuscript form.

11,000 + 1,000 = 152,000. Applying the 262/1,000 estimated prevalence of severe, irreversible noncardiac disease (1) that would exclude potential candidates from consideration, we have 0.262 x 152,000 = 39,824, the latter being the number of candidates who would be excluded. Their exclusion leaves 152,000 — 39,824 = 112,176, or approximately 112,000 candidates of all ages.

Maximum Age Considerations

According to the National Center for Health Statistics (NCHS), the following percentages of all cardiac deaths occur at the ages listed:

<80 years. 75%
<75 years. 57.5
< 70 years. 42
<65 years. , , ...30

From the application of cardiac deaths to the 112,000 candidates of all ages, we derive the following numbers of candidates:

< 80 years. 84,000
< 75 years. 64,400
< 70 years. 47,000
<65 years. 33,600

Thus, our estimate is that there would be 33,600 artificial heart candidates each year under the age of 65. Our estimate is not much different from the 1969 Ad Hoc Task Force on Cardiac Replacement's estimate, based on different assumptions and calculations, that there would be 32,168 candidates each year under the age of 65(l).

Patient Access to Implant Hospitals and Patient Refusal

We estimate above that 33,600 persons would be candidates for artificial heart implantation each year if all had access to hospitals capable of implanting an artificial heart and if all agreed to the replacement.

If the device is initially highly successful and/or if the patient selection criteria are relaxed overtime, as they have been for patients suffering from end-stage renal disease (ESRD), this figure might increase substantially. To allow for this possibility, we submit an "upper bound" of twice this estimate, or approximately 66,000 candidates.

Conversely, if large and intractable technical or other problems are encountered and/or if many potential candidates choose not to accept treatment with this device, the number of candidates might be substantially lower. Accordingly, we suggest a "lower bound" estimate of 16,000 candidates.

ECONOMIC ASPECTS

The economic costs of diagnosis, implantation, and postoperative care for artificial heart recipients are not easily predictable from present artificial heart prototypes, because there have been only a few human implantations and none of a totally implantable device. To provide a range of estimates, therefore, in the discussion that follows, we review the current cost information for three related medical technologies: 1) cardiac pacemakers, 2) coronary artery bypass graft (CABG) surgery, and 3) cardiac transplants. Data on projected device costs for the artificial heart were obtained from letters and interviews with manufacturers, as well as NHLBI reports. Three estimates of the major items of expense associated with artificial heart implantation and use are presented in table 1 on page 11. Following that are a discussion of personnel and facilities and a discussion of funding for R&D.

Artificial Cardiac Pacemaker

The implantable cardiac pacemaker is a complex device that, like the artificial heart, joins physicians with engineers and manufacturers. The first totally implanted pacemakers were reported in Sweden in 1959 and in the United States in 1960 (17,37,78). Clearly, the pacemaker is a clinical success. It has been dramati-

cally lifesaving and has enormously improved the quality of life for patients with heart block and other abnormalities of conduction. For purposes of this analysis, however, we are concerned with the costs, reliability, and longevity records of pacemakers. (For additional information, see app. A.)

From the outset, manufacturers of cardiac pacemakers predicted that energy stored in the battery would provide 5 years of pulse-generation function. This 5-year figure was based on battery capacity and calculated discharge rates; it did not include an allowance for the replacement of the pulse generator alone. Although some investigators expressed reservations about heightened expectations (78), there was a consensus that a 5-year pacemaker was at hand (17,37). That projection proved overly optimistic. Early battery failure necessitated pacemaker replacement in 60 percent of pacemaker recipients within 3 or 4 years. Even as late as a decade after the therapy became accepted, many pulse generators required replacement at 18 months. In addition, wire fractures, high thresholds, other component failures (e. g., self-discharge within the battery, inward leakage of body fluids), and infection required reoperation in about 30 percent of pacemaker recipients within 3 years (55,56). The predicted longevity was not achieved until 1975, with the availability of new battery technology (lithium).

The unanticipated complications of systems failures and recalls for recipients of cardiac pacemakers meant greater than estimated continuing care costs. Although the expectation had been for 3 to 5 years of fault-free system performance, the average system longevity during the first 3 years of pacing was only about 6 months. Some patients had in excess of 15 operations in 3 to *5* years.

A 1976 study (74) analyzed the financial records of patients with more than 4 years (an average of 73 months) of cardiac pacing to establish basic cost figures. A cost estimate of $7,500 includes an average of $3,500 for the initial implantation and ***$4,000*** for continuing pacemaker maintenance costs. Modern followup methods, apart from complications requiring hospitalization and operative repair, are also costly. Electronic monitoring, directly or indirectly by telephone, represents the best available means of followup. Electronic monitoring by telephone promises to reduce the number of emergency admissions, but the procedure is costly. Third-party payers, Blue Cross and medicare, now pay $30 per telephone call; most patients are monitored twice monthly, some as often as weekly. Thus, the monitoring cost can approximate $1,560 per year.

Coronary Artery Bypass Grafts

The costs of CABGs have become an issue as the number of procedures has grown—from 20,000 in 1971, to 50,000 in 1974 (75), to an estimated 70,000 in 1977 (11), to 100,000 in 1978 (47). Figures from several studies analyzing surgical costs of CABG patients (24,32,47,59,75) were updated with assumptions about patient care for artificial heart recipients to arrive at the figures given in column A of table 1.

A study by Befeler (11) presents the range of costs for 20 CABG patients. Hospital charges for a 17-day average stay ranged from $6,525 to $22,142, for an average of $10,103. This figure includes charges for EKG analysis, cardiac catheterization, blood flow rate measurements, and other hospital fees that would be incurred by artificial heart recipients. The professional fees incurred by CABG patients provide the most recent comparable cost information for professional fees that might be incurred by artificial heart recipients. The surgeon's fee for CABG currently ranges from $2,000 to $2,400, averaging $2,200; the anesthesiologist's fee averages $974; and the cardiologist's fee averages $652. This brings the average professional fees for CABG to $3,826. When these fees are added to the hospital costs of CABG surgery, the total charges are $13,929. Allowing for inflation and national variation, we estimate an average cost of $15,000 for CABG surgery.

Heart Transplants

Recent successes in cardiac transplantation at Stanford University Medical Center provide a

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third cost comparison. Between 1969 and June 1979, Stanford completed 179 cardiac transplants, with 71 survivors (62). The survival rate of patients who receive heart transplants now rivals that of patients who receive kidney transplants from unrelated donors. About 70 percent survive to 1 year, and 50 percent survive afters years. The heart transplant patient selection criteria at Stanford are very stringent. Selection is based on factors that include the absence of infection, a psychological evaluation, and economic criteria. Patients must show they can provide transportation to and from Stanford during postoperative monitoring and must document that the patient's family can provide financial support during this period. Many of the recipients are young. Of 13 patients between 12 and 21 years old, 7 are still alive, with a 64-percent survival rate to 4 years.

In February 1980, the former National Center for Health Care Technology (NCHCT) recommended that the Health Care Financing Administration (HCFA) reimburse cardiac transplantation at Stanford under medicaid. Previously, a substantial portion of the costs was underwritten by the National Institutes of Health (NIH). A full recommendation on medicaid reimbursement for heart transplants is being prepared that will include suggestions for cost containment incentives, "distributive justice" issues for patients unable to afford the transportation to and from Stanford, and a consideration of whether it is necessary to regionalize (limit to four or five centers) heart transplants. '

Average costs for cardiac transplantation at Stanford in 1977 are listed below (62):

Transportation and lodging	$ 5,600
Evaluation cost	3,500
Hospital costs	62,000
Professional fees	30,000
Total	$101,100

These figures for cardiac transplantation do not include fees for the heart donors, which would not be encountered in artificial heart surgery. The largest contributing factor to the total cost of cardiac transplantation is the length of hospital stay, which averages 65 patient days. The average daily costs are between $400 and $500 (not corrected for inflation). The first 30 days after surgery are spent by cardiac transplant patients in intensive care at the highest service intensity and costs. Much of artificial heart implantation would be emergency surgery, according to our earlier patient selection pool, and charges for transportation and lodging would not be incurred. We have deducted these charges and reduced the hospital charges for cardiac transplantation by one-half (to account for the shorter hospital stay and fewer laboratory tests required by artificial heart patients) to arrive at the figures given in column C of table 1.

The annual cost of followup care for heart transplant patients at Stanford, after the first year, is approximately $8,800 (62,71). Inpatient followup care (medical surveillance, chest X-rays, lab tests, and EKGs) costs about $7,300, and outpatient followup care about $l,500. The higher continuing care costs for the first year and for those eight patients at Stanford who have had second heart transplants are not included in the maintenance figure. (Tables summarizing the inpatient and outpatient costs at Stanford are provided in app. B.)

Device Costs

Estimates of the cost of the artificial heart itself vary, depending on the energy supply. The following four energy supply systems are discussed in the report of the 1973 Artificial Heart Assessment Panel (51): 1) electrically powered, internal heat energy storage, 2) long-term internal secondary battery, 3) external secondary battery, and 4) nuclear power.

Two of these energy systems are used on LVADS that are undergoing testing and research today. One is an electrical-energy converter powered by an electrochemical battery. The other is a thermal-energy converter powered by an electrical or radioisotope-charged battery. Recent estimates of the future cost of these LVADs from NHLBI contractors provide the best proxies for what the potential cost of the artificial heart may be when, and if, it is mass produced. According to representatives from Ther-

' *The Blue Sheet,* Feb. **20, 1980.**

moElectron and Aerojet-General, an electromechanical LVAD designed for 2 years of reliable use, at a production level of 5,000 per year, will cost an estimated $10,000. A 5-year device may cost $13,000 or $14,000. In addition, the batteries for such a device will cost several hundred dollars a year. An LVAD driven by a thermal engine will cost an estimated $14,000, with no additional costs expected for a 5-year reliable form.

Willem Kolff, at the University of Utah, estimates that the first totally implantable artificial hearts will be air-driven and will cost around $14,000. However, many technical problems remain to be resolved (e.g., the development of reliable biomaterials), and costly solutions would increase these figures.

There is little potential for declining costs with mass production of the devices because of the high level of reliability demanded for the devices and the expensive marketing structure. Theodore Cooper, former director of NHLBI, confirmed this point in a 1979 interview (22), stating that he does not expect artificial hearts to be produced on a competitive basis; therefore, saturation and declining costs for the device are not apt to be realized.

Summary of Costs

Table 1 contains three estimates of the major items of expense incurred in the diagnosis, implantation, and recovery of patients undergoing artificial heart implantation. These items have been discussed in the preceding sections.

Our lower bound cost estimate (A in table 1) is based on the CABG proxy, a low estimate for the device of $10,000, and a low estimate for continuing care of $1,500 based on the experience of cardiac pacemakers. * We do not expect the technological and continuing surveillance needs of artificial heart recipients to be less than emergency medical treatment and monitoring costs of cardiac pacemakers. In addition to incurring these continuing medical costs, recipients will have to replace batteries yearly for the 2-year reliable LVADs that are being developed. ** These batteries will cost about $300 to $500 annually.***

Table 1.—Three Estimates of Major Items of Expense Associated With Artificial Heart Implantation and Use

Item of expense	A CABG proxy[a]	B Calculated fees	c Cardiac transplant proxy[b]
Implantation			
Hospital care	$10,103	$10,822	$31,000
Professional fees	3,826	5,300	30,000
Device costs[c]	10,000	12,000	14,000
Total	$23,929	$28,122	$75,000
Continuing costs[d]			
Medical care	$1,500	$2,000	$8,800
Batteries	300	300	—
Total yearly	$1,800	$2,300	$8,800

[a] CABG proxy for costs of hospital care and professional fees; cardiac pacemaker proxy for costs of continuing medical care.
[b] Cardiac transplant proxy for costs of hospital care (adjusted), professional fees, and continuing medical care.
[c] Based on estimates for electromechanical LVAD.
[d] Annual costs subsequent to implantation.

SOURCE: Estimates are derived from information provided in the text.

Our second cost estimate (B in table 1) is based on our own calculations using current hospital costs, professional fees, and a middle estimate of $12,000 for the device. Consultations with cardiac surgeons suggest that the nonemergency patient will need to be hospitalized for 5 to 7 days prior to artificial heart implantation. Immediately after surgery, the patient will be placed in an intensive care unit for extensive monitoring and treatment for an anticipated period of 7 days. Normal progression of the recovery processes would be expected to require a hospital stay of about 21 days. Combining these length-of-stay figures with current hospital costs, we calculate that the recipient of an artificial heart would incur total hospital costs of $10,822. That total includes $6,300 for 28 days of care (7 days preoperatively, 21 days postoperatively) at $225 per day* and $4,522 for 7 days of intensive care at $646 per day.**

● There is a considerable difference of opinion about continuing cost estimates. One reviewer felt that both the cardiac transplant and pacemaker continuing costs were too *high.* Another reviewer felt that there would be numerous mechanical problems, so that even cardiac transplant estimates were *too Zow.* In table 1 we have presented a range of estimates, with $8,000 as the upper bound.

**See section on LVAD research below for a description.
***Estimate from Thermoelectron.
*Cost figures from the American Hospital Association.
**The amount reimbursed by the Health Care Financing Administration (HCFA) for intensive care.

We have added the professional fees stated for CABG patients ($3,826) and applied them to the surgical demands of artificial heart implantation. * The amount increases, because of the anticipated need for an associate surgeon (fee of $500) and two anesthesiologists, to $5,300.** When we add these fees to the hospital costs, we arrive at estimated charges of $16,122, well within the range of coronary bypass surgery. (Many of our interviewees compared implantation costs to present bypass costs.) Following hospitalization and discharge, the artificial heart recipient would presumably spend a reasonably prolonged period of recovery. We anticipate that during this recovery period the patient will require frequent visits to the physician at the hospital where the surgery was performed. For this reason, we expect the first year's costs to be similar to those for cardiac transplant patients, but we have chosen a lower continuing cost figure of $2,000.

Our upper bound estimate (C in table 1) employs the cardiac transplant figures described earlier. The only addition is the device figure of $14,000 for an air-driven heart, which would not require batteries.

It must be noted that for all three estimates we assume no surgical complications such as thrombosis, hemorrhage, and circulatory insufficiency. Such complications would require a longer hospital stay and could easily double the hospital costs.

● In an experimental procedure, professional fees are not ordinarily charged. However, *once* the artificial heart is deemed to be therapeutic, these fees will be incurred.

● *See discussion of personnel and facilities in the next section of this case study.

In summary, the hospital and implantation costs to the recipient of an artificial heart may approach the present fees associated with cardiac transplants and will certainly be higher than the present costs of CABG surgery. Table 2 lists varying total societal costs for the range of biologic or mechanical heart implants discussed in the previous section of this case study and also shows the impact on present facilities and personnel. Even the best estimates project an expense that an individual recipient would not be able to afford completely and that private insurance schemes would be expected to reimburse only partially (as with dialysis and heart transplants). To meet these expenses, which could easily reach $3 billion annually, the Government will have to consider new concepts in insurance or social security coverage.

Personnel and Facilities

An important consideration in planning for the clinical application of the artificial heart is the adequacy of present medical facilities and surgical teams. The agonizing selection of patients associated with the early days of hemodialysis points up the problem that a shortage of facilities and skilled personnel may create if preparations for the artificial heart are inadequate.

John Watson, Chief of the Devices and Technology Branch of NHLBI, believes that existing open-heart facilities should be adequate for artificial heart surgery and postoperative recovery (77). The growth in emergency cardiac facilities and personnel during the last decade and the plans for mobile care units and coronary facilities throughout the United States should pro-

Table 2.—Effect of Numbers of Implants on Available Societal Resources

Replacements per year	Total costs per year (in millions) with implantation costs of:			Implants per surgeon per year with number of available surgeons:			Implants per facility per year with number of available facilities:		
	$24,000	$28,000	$75,000	800	1,000	1,200	600	800	1,000
16,000	$ 384.00	$ 448.00	$1,200.00	20.0	16.0	13.3	26.7	20.0	16.0
33,600	806.40	940.80	2,520.00	42.0	33.6	28.0	56.0	42.0	33.6
47,000	1,128.00	1,316.00	3,525.00	58.8	47.0	39.2	78.3	58.8	47.0
66,000	1,584.00	1,848.00	4,950.00	82.5	66.0	55.0	110.0	82.5	66.0

SOURCE: Estimates are derived from information provided in the text.

vide a facilities base suitable for the transportation of candidates for artificial heart surgery. As noted below, however, artificial heart implantations may severely strain existing personnel resources.

Interviews with cardiac surgeons indicate that the services of the current open-heart procedure team plus an associate surgeon and an artificial device engineer will be required for artificial heart implantation. The estimated personnel requirements in the operating room are listed below:

	Hours
Chief surgeon	4-5
Associate surgeon	2-3
Anesthesiologists (2)	7-8
Heart-lung machine operators (2)	7-8
Residents (3)	7-8
Nurses (3)	7-8
Technicians (2)	7-8
Artificial device engineer	4-s

These personnel requirements are extensive when superimposed on present needs for skilled surgeons and nurses for heart-lung work, heart transplants, arterial grafts, and pacemaker implantations. Artificial heart surgery, like heart transplantation, is likely to disrupt any hospital's schedule. In addition, the surgery is only a small part of the patient care process, which requires the time and resources of nurses, lab technicians, physicians, and engineers.

It is difficult to estimate the present number of cardiac surgeons, because currently available medical specialty statistics do not differentiate between cardiac and noncardiac thoracic surgeons. In 1976, there were 2,020 thoracic surgeons (3). Approximately 39 percent (780) are estimated to be active cardiovascular surgeons. The supply of cardiac surgeons has been increasing at about 15 percent per year (59), so shortly almost half of certified thoracic surgeons will be active in cardiac surgery. Using these figures, we have assumed that as few as 800 and probably closer to 1,000 surgeons will be available to perform artificial heart surgery in the coming decade.

In 1976, an estimated 600 hospitals were engaged in open-heart surgery, an increase from 432 hospitals in 1972. Under the assumption that no new facilities would be required for artificial heart implantation, if one postulates a total of 33,600 implants a year* and 800 hospitals have cardiac facilities, each hospital would average 42 implants per year. These centers will also have subsidiary concerns, among them the blood requirements necessary to prime the heart-lung machine for surgical bypass and emergency care of hemorrhage, pump oxygenators, and an inventory of artificial hearts available for immediate use. With a product whose demand could vary from 16,000 to 66,000 per year and whose reliability, longevity, and maintenance record still remain undocumented, accurate estimates of the major resource requirements are still not feasible.

R&D Funding

The NHLBI-directed program for the development and assessment of circulatory-assist and cardiac replacement devices is partially funded through contracts (see app. C). This family of contracts provides funds for researching blood pumps, power sources, energy transmission and storage, instrumentation, and biomaterials. There is no single major recipient of contract funds. As shown in table 3, the targeted contract program of the Devices and Technology Branch grew rapidly from $500,000 in fiscal year 1964 to $8 million by fiscal year 1976. Since then, the program has remained relatively stable at an average of $10 million a year. Figure 1 compares relative funding levels for NIH, NHLBI, and the artificial heart program for fiscal years 1964 through 1975.

NHLBI has also supported basic research for the artificial heart development program through extramural grant programs. The extent of these funds is difficult to delineate in the overall Institute grant figures. The responsibilities of the Devices and Technology Branch were broadened to include grants in 1975. Activities funded through regular and project grants include intra-aortic balloons, biomaterials, and prosthetic heart valves (see app. C). The branch also has unrelated grant activities on

*The manner of arriving at this estimate was discussed in the previous part of this case study.

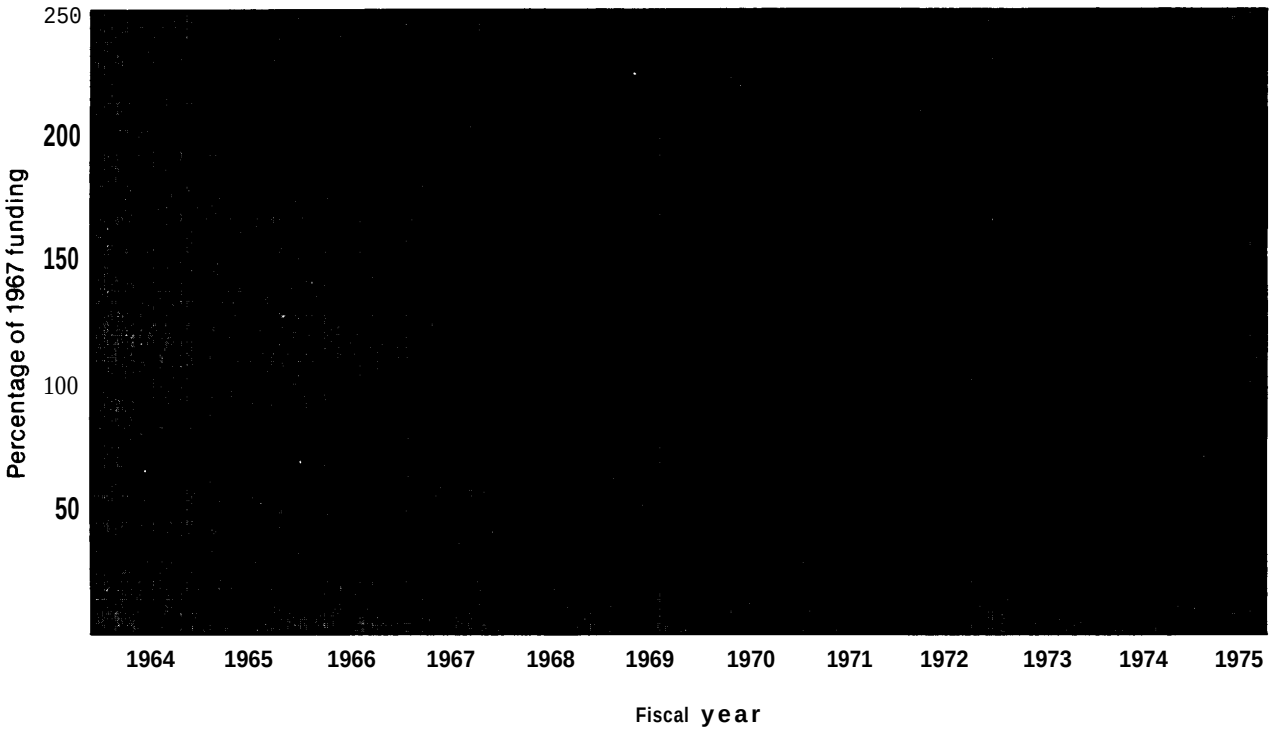
Table 3.—NHLBI Devices and Technology Branch Contract Funding, Fiscal Years 1964-79

Fiscal year	Programs							Total
	Materials	Energy systems	Blood pumps	Bioinstru-mentation	Special programs	Oxygenators	Physiological testing	
1964	$ 209,085	$ 93,856	$ 278,183	$ 0	$ 0	$ 0	$ 0	$ 581,124
1965	0	0	0	0	261,756	0	0	261,756
1966	843,242	728,500	316,555	0	1,680,857	0	335,777	3,904,931
1967	1,735,469	2,909,378	1,377,433	0	898,406	467,747	1,165,876	8,554,309
1968	2,130,569	1,365,749	1,533,379	617,456	149,818	590,440	1,454,113	7,841,524
1969	1,062,462	2,902,329	1,345,945	479,833	239,012	495,766	1,862,252	8,387,599
1970	1,089,083	2,660,840	1,476,869	312,657	9,000	338,460	3,388,334	9,275,243
1971	1,115,375	3,165,036	1,793,847	146,023	446,757	676,786	1,873,712	9,217,536
1972	905,044	3,897,469	2,386,193	251,386	62,548	381,161	2,700,718	10,584,514
1973	1,877,930	2,822,000	1,971,222	183,513	42,500	43,848	2,996,743	9,937,756
1974	557,214	3,471,258	2,466,405	560,030	44,978	0	851,655	7,961,540
1975	440,069	3,480)204	3,448,612	1,707,659	0	0	56,196	9,132,740
1976	3,274,000	3,182,000	3,082,000	1,492,000	908,000	0	0	11,938,000
1977	3,259,000	3,883,000	3,098,000	2,040,000	921,000	0	0	13,201,000
1978	2,373,000	4,034,000	2,899,000	2,235,000	577,000	0	0	12,118,000
1979a.	1,700,000	3,700,000	3,300,000	1,800,000	500,000	0	0	11,000,000
Total. . . .	$22,571,542	$42,295,619	$30,773,643	$11,835,557	$6,741,632	$2,994,208	$16,685,376	$133,897,577

[a]Estimated.

SOURCE: National Heart, Lung, and Blood Institute, Devices and Technology Branch, Bethesda, Md., 1979

Figure I.—Comparative Program Growth: NIH, NHLBI, and the Artificial Heart Program, Fiscal Years 1964-75



SOURCE: National Heart, Lung, and Blood Institute, Bethesda, Md.

diagnostic instruments and therapeutic devices. John Watson, of NHLBI, has estimated total grant spending since 1964 at $30 million. For fiscal years 1977 through 1979, the grants specifically related to the development of the artificial heart were $10 million. Approximately $3.5 million in grants were funded in fiscal year 1978.

The $164 million spent to date on the NHLBI artificial heart program ($134 million in contracts, $30 million in grants) represents the bulk of the total cost of developing an artificial heart, but several research institutes and technology firms have held Department of Energy (DOE) contracts (totaling $17 million) to develop a nuclear engine for an LVAD or totally implantable artificial heart. Contractors include the University of Utah, Westinghouse, Andros, Arco, and Aerojet-General. We have estimates from only one contractor on the size of these funds, though we have contacted other recipients for information. That firm has spent almost $7 million to date on thermal energy development. The financial history of the artificial heart program at DOE is summarized in table 4.

In 1968, the Atomic Energy Commission (AEC), now DOE, initiated a program at Los Alamos Scientific Labs for the development of plutonium-238 (Pu-238) fuel for the artificial heart. In 1971, contracts were awarded to several university research centers (University of Utah, Cleveland Clinic, University of Washington) to begin biomechanical and biomaterials studies. According to Donald Cole of DOE's Office of Health and Environmental Research (20), DOE funding has recently ended.

It is by no means clear, however, that interest in nuclear energy as a power source for the artificial heart has ended. In early 1979, NIH solicited proposals for research into a clinical thermal energy system, and in November 1979, 3-year contracts for $900,000 and $795,000, respectively, were awarded to Aerojet-General and the University of Washington. The thermal engine to be designed can be driven by one of two energy sources: thermal (e.g., lithium salts) or nuclear (e. g., Pu-238). Of these two sources, Pu-238 is acknowledged to be clinically the more attractive, because lithium salts must be reheated at intervals not exceeding 4 to 8 hours.

Table 4.—Financial History of the Artificial Heart Program at the Department of Energy

Contractor	Period of performance	Title	Cumulative costs
Westinghouse Electric Co.	4/19/71 - 6/30/78	Nuclear-powered artificial heart	$10,005,103
Hittman Associates	3/74 - 3/75	Development of a radioisotope heat source subsystem for heart devices	16,000
Universities Center.	8/1/73 - 7/31/74	Artificial heart controls support	19,033
University of Washington	6/15/71 - 9/14/78	A program to evaluate the mechanical properties and biocompatibility of materials for the ERDA artificial heart	457,883
TRW, Inc.	4/19/71 - 6/30/75	Radioisotope heat source for an artificial heart	527,499
Cleveland Clinic	2/15/72 - 12/31/77	Artificial heart supporting services	257,499
Cornell University.	9/74 - 9/30/78	Biological effects of implanted nuclear energy sources for artificial heart devices	371,666
Sinai Hospital	9/1/75 - 8/31/76	ERDA artificial heart program review	9,874
University of Utah.	6/15/71 - 6/30/79	Biomedical engineering support	1,719,880
University of Utah.	6/15/71 - 9/14/77	Materials testing and requirements for the ERDA nuclear-powered artificial heart	357,208
Westinghouse Electric Co.	5/1/72 - 4/30/73	An investigation of high-performance thermal insulation systems	132,421
Los Alamos Scientific Laboratory.	7/1/72 - 9/30/77	Fuels and source development	2,083,000
Mound Laboratory	7/1/72 - 6/30/73	Fuels and source development	59,000
Pacific-Northwest Laboratory.	7/1/72 - 6/30/74	Recipient radiation exposure	163,000
Pacific-Northwest Laboratory.	7/1/72 - 9/30/77	Population radiation exposure	145,000
Pacific-Northwest Laboratory.	7/1/73 - 10/1/76	Pu-238 from Am-241	315,000

SOURCE Information provided by the Department of Energy, Washington, DC.

In addition to Federal contracts and grants, some private funding helps to support artificial heart research. For example, the Cleveland Clinic has an NHLBI contract to develop a pump suitable for an implantable LVAD. Supplementing this contract, Parker-Hannifin Corp. provides a philanthropic gift that covers approximately 10 percent of the clinic's heart device research. TRW Corp. produces at its own expense components that are contributed to the clinic. Goodyear Corp. contributes expertise and manufactures the diaphragm for the pumps. It also contributes one full-time employee who works on the clinic's heart device program. This support is part of Goodyear's Aid to Medical Research Program. The Cleveland Clinic is also testing Medtronics' LVADs with that firm's equipment, service, and expertise. Testing and clinical trials of these devices are separate from NHLBI funding.

Federal allocations for the artificial heart program have averaged $10 million since 1964, and the present annual figure is approximately $15 million in contracts and grants. The growth in allocations has not kept up with requests or inflation. Some researchers, such as Yuki Nosé of the Cleveland Clinic, have estimated that a clinically useful, totally implantable LVAD may be ready in 1983, and that a totally implantable artificial heart may possibly be available in 1986. Other contractors say these estimates are optimistic, given present funding, and some claim that a totally implantable artificial heart may not be ready until the year 2000. It could happen, then, that federally funded research will be required for another 10 years. If annual allocations are held at the present level for 10 years, this means an additional $150 million in Federal R&D funds—and $300 million is a potential figure if research continues until the end of the century.

PARALLEL COSTS OF HEMODIALYSIS

Hemodialysis and kidney transplantation emerged as life-extending therapies for victims of ESRD in the early 1960's. Here we examine the experience of hemodialysis financing and distribution in order to draw lessons that have potential for application to the artificial heart.

Systematic funding efforts by NIH on behalf of the kidney program began in 1965 (64). At that time, the artificial kidney-chronic uremia program of the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD) was founded with a contract research program to build a better artificial kidney. The artificial kidney program was mandated by the House and Senate Appropriations Committees with the 1966 budget, 1 year after the artificial heart program was founded in the National Heart Institute. Though the artificial kidney was advanced well beyond the artificial heart at the time, advocates of the artificial heart (such as Michael DeBakey) appear to have been more powerful.

Human kidney transplantation, which following occasional attempts in the 1940's had begun in earnest in the 1950's, developed in parallel with the artificial kidney. The availability of hemodialysis helped the kidney transplantation program by making available pools of potential transplant recipients. NIH funding was available for transplantation research, because the researchers who worked on the immunological problem were well known as basic researchers (64). Information concerning the total sums spent on development of artificial kidney technology or kidney transplantation is not readily available.

In 1960, cost estimates for hemodialysis were made by Belding Scribner and his colleagues at the University of Washington in Seattle (63,64). Minus equipment, the cost per patient for once-weekly dialysis was estimated to be $5,533 annually. The later recognition that dialysis three times weekly would be better medically greatly

increased per patient costs (63). In 1963, at a joint finance meeting of the American Medical Association and the National Kidney Disease Foundation, costs were estimated to be about $20,000 per patient per year. The moral questions involved in the availability of dialysis were brought up at the same meeting. There was concern that 25 to 50 percent of those who needed dialysis were not able to obtain it (43).

In 1964, the Federal Government recognized its potential fiscal role in treatment of ESRD, and the Senate Appropriations Committee said that the Public Health Service (PHS) had the authority to provide demonstration and training funds for artificial kidney programs (but not for patient care) (63). Scribner and his colleagues in Seattle, through community fundraising and private philanthropy, had developed a community treatment center in 1962. The first PHS demonstration and training grant had been given to that center in 1963 (63), to be phased out in 3 years. Also in 1964, NBC television was preparing a documentary that was aired in 1965 contrasting the millions the Government was willing to spend on the space program to the small amount spent for dying individual in need of dialysis. A total of $3.4 million was allotted for support of 14 community dialysis centers. In 1968 and 1969, PHS took action to gradually stop funding these centers.

In 1967, despite these efforts, the Gottschalk committee (an advisory group convened by the Bureau of the Budget) recommended Federal financing of patient care for ESRD through an amendment to the medicare component of the Social Security Act. One month prior to the 1972 election, Congress passed the Social Security Amendments including section 2991 which extended medicare coverage to the treatment of ESRD. Section 2991 was allotted less than 30 minutes of discussion on the Senate floor and given only a few minutes of deliberation in the joint House-Senate Conference Committee. President Nixon signed it into law on October 30, 1972 (63). Senator Vance Hartke, who sponsored section 2991, stated that estimated annual costs at the end of 4 years would be $250 million, with a first year cost of ***$75*** million (63). *

Ronald M. Klar, in the Office of the Assistant Secretary of Health at the Department of Health, Education, and Welfare (HEW), immediately saw problems with this estimate. Through information obtained from nephrologists, Klar made new projections of the costs of the ESRD program based on a new cohort of patients entering the program each year. Each cohort would include about 10,000 patients, 2,000 of whom would be transplanted; there would be about a 20-percent annual mortality rate; and the average annual cost of dialysis would be $16,000. Thus, according to HEW in 1972, the cost in 5 years would be an estimated $592.1 million for 40,000 patients. By the time the program stabilized in 10 years, the cost would be $1 billion annually (64). Table 5 summarizes the 1972 HEW and 1974 Social Security Administration (SSA) estimates of the annual costs for the ESRD program (64).

The House Ways and Means Committee, in 1975, estimated there would be 50,000 to 60,000 patients by 1984 at a cost of $1 billion, and

*The Senate amendment included a 6-month waiting period for patients before benefits should begin, which the House Ways and Means Committee was able to change to 3 months.

Table 5.—Estimated Annual Costs for the ESRD Program (dollars in millions)

Fiscal year	Total patient population	SSA estimates of medicare expenditures (1974)	HEW estimates of total national costs (1972)
1974	9,980	$135	$157.7
1975	18,754	176	281.5
1976	26,746	223	394.5
1977	34,036	278	497.8
1978	40,685	—	592.1

SOURCE: R.A. Rettig and T. C. Webster, "Implementation of the End-Stage Renal Disease Program: A Mixed Pattern of Subsidizing and Regulating the Delivery of Medical Services, " 1977 (64),

50,000 to 70,000 patients by 1990 at a cost of $1.7 billion (64). According to Barnes (9), the National Dialysis Registry estimates an annual mortality rate of only 10.8 percent for patients on dialysis during the first 4 years of care. Since the highest mortality rate occurs in the first year, this estimate is in marked contrast to the estimate of a 20-percent annual mortality rate of the Office of the Actuary of the SSA noted above.

A number of problems have occurred with regard to cost estimates for the ESRD program. Both Barnes (9) and Rettig (64) address them thoroughly. We summarize the most important points below.

- There has been persistent underestimation of total costs.
- The early hope of increased success with cadaveric transplantation has not been realized.
- The increased problem of poor quality of life for patients and the small proportion rehabilitated was not anticipated. *
- Cost-reducing innovations in therapy through R&D have not occurred.
- Prospects for disease prevention seem remote.
- The least expensive mode of treatment, home dialysis, is not being used as extensively as expected. Some of this problem is the result of taking marginal patients such as the elderly and diabetics, as well as the result of economic disincentives for home dialysis by patients and physician providers.

The artificial heart program has received more Federal research money than the hemodialysis program did at equivalent stages of development. Early meetings of the American Society for Artificial Internal Organs saw development of an artificial heart as much more complex than that of an artificial kidney, because a permanent, complete artificial heart must constantly perform the full and precise function of the human heart, whereas a kidney can function part time and at a comparatively low capacity.

Anderton, et al. (4) have concluded that there is no positive economic benefit for the treatment of renal failure. In paying for such treatment, society is tacitly agreeing to pay for the intangible" benefits of avoidance of pain, discomfort, grief, and premature loss of human life. For the artificial heart program, the dialysis experience indicates that the allocation of scarce medical resources for the saving or prolonging of lives deserves thoughtful deliberation.

*Quality of life parameters are discussed below in another part of this case study.

**In economics, "intangibles" are those *costs* and benefits that cannot be quantified or priced.

ESTIMATES OF THE POTENTIAL SUCCESS OF THE ARTIFICIAL HEART

LVAD Research and Clinical Trials

Since its inception, the artificial heart program has advocated simultaneous research on both permanent heart replacement and temporary LVADs. Because of the obstacles encountered in developing a totally implantable artificial heart, however, the development of the LVAD now takes priority. NHLBI funding since 1974 has been largely concentrated on the development of LVAD control systems, pump design, biomaterials, and beginning in 1975, clinical trials.

The goals of the LVAD program center at present on developing a long-term (2- to 5-year) implantable LVAD capable of taking over the pumping function of the weakened left ventricle of the heart and enabling its eventual recovery. The development of a long-term assist device will draw heavily on current experience with the temporary (2-week) LVAD. Many models of the temporary LVAD currently exist; these have been funded largely through NHLBI,[2] but partly

[2]See Report of Cardiology Advisory Committee, *Journal of Artificial Internal Organs (JAIO)*, November 1977, for summary of NHLBI devices.

through independent corporate investment (e.g., by Medtronics and Arco Medical Products). Because of the recent emphasis on developing a long-term implantable LVAD, explicit funding of total artificial heart development has been much less extensive; in 1978, NHLBI had only four total artificial heart contracts, totaling $1 million.

In 1974, NHLBI convened a workshop to consider the desirability and feasibility of conducting LVAD clinical trials. Ruth Hegyeli and Michael Machesko, 1974 workshop participants, reviewed in vitro and animal data on the Thermoelectron LVAD (TECO models VII and X) used by John Norman of the Texas Heart Institute and William Bernhard of Boston Children's Hospital (34). They concluded that clinical trials would be in order once biomaterials suitable for short-term use were developed, adequate provisions were made to protect patient/subject rights, and criteria were established for patient selection.

After meeting these criteria, Norman and Bernhard received funding from NHLBI for clinical trials of the short-term (2-week) LVAD. Both the Texas Heart Institute and Boston Children's Hospital trials used the same patient selection protocol, which sets forth a number of conditions to be met by potential LVAD recipients. Only patients unable to resume cardiac function at the conclusion of cardiac pulmonary bypass were included. A total of 38 implants (23 Texas, 15 Boston) were performed in this program (58). Three patients were alive at this writing (May 1980), 25, 24, and 18 months after surgery; one patient survived 7 months. Of the last 14 implants, 8 were successfully supported for more than 40 hours (77). *

In addition to the NHLBI clinical trial contract program, several other clinical trials of different LVAD models have taken place.** William Pierce, of Pennsylvania State University, has used a smooth-surfaced, polyurethane-coated pump in approximately nine patients and reported the first long-term survivor (57). Limited clinical use of other LVADs in at least 11 patients has been reported, with 2 long-term survivors (57). The extent of use of commercially developed pumps (e.g., Arco, Arothane) in therapeutic settings is unknown, because data from these implants are not formally reported.

Those who have conducted LVAD clinical trials believe they have obtained much valuable information that will contribute to the successful development and use of future long-term devices. Such information includes confirmation of the hypothesis that temporarily taking over the left ventricle pumping function can, in some patients, lead to partial recovery of the depressed ventricle and the observation that right heart function is not always necessary during LVAD implantation (52).

Major problems in device design and function still exist, however. A primary challenge is the development of biomaterials that do not encourage thrombogenesis (formation of blood clots) and do not decompose over long-term use. Another challenge is the development of a portable, reliable energy source. Current prototypes using electric batteries have both mechanical and operational liabilities; Pu-238-powered fuel cells provide a compact energy source but pose severe problems due to health risks from radiation.***

NHLBI has given top priority to further research in the areas of biomaterials and energy sources (16). A special biomaterials task force issued recommendations in 1977 calling for the exploration of the comparative viability of rough and smooth surfaces, the development of operational and quantitative definitions of blood compatibility, theories that correlate blood compatibility with physiochemical characteristics of biomaterials, and adequate test and evaluation methods. There has been progress in these areas, and advances will increase as NHLBI grants for basic research in biomaterials expand. Because of the magnitude of the technical problems that must be solved in order to develop a long-term (2-year) LVAD, estimates for commencement of clinical trials of the long-

*A summary of the clinical trial program is currently being developed by NHLBI.

For example, see articles in the **1978 issue of JAIO devoted exclusively to LVADS.

***The problems of a nuclear-powered heart are discussed below in a separate section of this case study.

term LVAD range from 3 to 6 years. Industry representatives (Thermoelectron and Aerojet General) note that even the 6-year estimate may be overly optimistic if the level of Federal funding does not increase.

Another factor complicating long-term device development is the diversity of existing LVAD programs and the difficulty of coordinating research or clinical trial results. Although data from NHLBI-sponsored LVAD programs have been difficult to compile, the existence of privately funded programs makes comprehensive data collection and coordinated research efforts even more difficult.

The experience of clinical trials of short-term LVADs appears to be of only limited use in projecting the potential success of permanent devices, in part because the research protocols restricted potential recipients to very ill patients who are likely to die regardless of the form of treatment. Because the devices are implanted temporarily, only short-term mechanical performance and negative side effects can be observed; medium- and long-term device performance and side effects cannot be evaluated. Since most patients die on the operating table from other causes, even potential complications due to the short-term device cannot usually be identified.

Instrument Reliability

Instrument reliability is of utmost importance in the effort to achieve a clinically successful totally implantable artificial heart. With the patient's natural heart removed, sudden instrument failure would lead to the patient's death within minutes unless corrected. Reliability is different from durability. The durability of the individual components of a device can be bench tested and predicted with some confidence (e.g., materials that will flex with every stroke of the heart pump can be tested for the enormous number of such flexions to which the materials will be subjected over the anticipated instrument life). The reliability of the assembled components under the conditions of use cannot be predicted from bench tests alone, and testing has not yet been done in animals. Testing, when begun, will have to extend for at least as long a period of time as the required life of the device and, perhaps, twice as long. * Thus, if the target is for a 5-year device, it will be necessary to wait for 5 to 10 years before reliability can be established. " Further, since the concept of reliability is a statistical one, large numbers of trials may need to be carried out.

Experience with other medical devices offers some basis for expectation and for concern. The cardiac pacemaker, an enormously less complex instrument, has presented a series of serious difficulties which, after nearly 20 years of clinical use, have only now been resolved with reasonable success. These include lead breaks, battery failure, runaway pacemakers, electromagnetic interference, and errors in manufacture as well as errors and complications in clinical application. *** The cardiac pacemaker is a simple, primarily electrical device with a low energy requirement. The artificial heart is a complex electromechanical device which has high energy and mechanical requirements. Although pacemaker failure is a serious complication, the patient often survives long enough for replacement. Failure of the artificial heart, however, would in almost all imaginable circumstances lead rapidly to death.

Our consultants express confidence that an appropriate energy source (e.g., battery) with 5 to 7 years predictable life is currently feasible. No such assurances have been offered for the mechanical components or for the artificial heart system as a whole. Opinions have been offered that a system life as short as 60 days or as long as a year may be encountered. Contributing to the uncertainty is the existence of a number of identifiable problems that have yet to be resolved.

● Accelerated aging at increased temperatures can be used to shorten the period of testing of implantable electronic devices but would not be appropriate under the hemodynamic conditions of the artificial heart. A method to shorten the test period for the artificial heart is urgently needed but cannot be counted on.

**In discussing this section, Kolff and others have pointed out that a device of even as little as 1-year reliability would be welcomed by many patients and physicians.

***See app. A by Dr. Thomas Preston for a summary of the introduction of the pacemaker and difficulties encountered; see also testimony of Sidney M. Wolfe and Anita Johnson on medical device legislation before the House Subcommittee on Health, July 28, 1975 and Oct. 23, 1973.

Such problems include permeability to moisture (undesirable) and to gases (desirable), and the need for volume and pressure compensation behind the moving pistons in a mechanically activated pump. It can be assumed that problems that cannot be identified at present will also present themselves.

QUALITY OF LIFE

The stated goal of every transplantation program is to return patients to active, productive lives. The experience of heart transplants, kidney transplants and. dialysis suggests that, while for many patients the quality of life is considered good, the replacement of a vital organ often produces unforeseen complications in other parts of the body. It is impossible to predict the spectrum of adverse outcomes that will be encountered with the artificial heart. Nevertheless, it may be possible to draw inferences concerning the chances for partial or total rehabilitation after implantation of an artificial heart by examining related experience with these other major surgical and medical interventions. Therefore, we examine that experience below. We also discuss the problems that might be associated with a nuclear-powered device.

Hemodialysis and Kidney Transplants

In general, short-term complications were expected very early in the use of dialysis. These included hemolysis, bleeding from heparinization, calcium disturbances, and electrolyte disturbances, It was only after a few years that renal bone disease, neuropathies, and hepatitis were seen (9). Some progress has been made with these problems, but accelerated atherosclerosis, dialysis ascites, and dialysis dementia (an acute deterioration of cerebral function) remain. In the United States, 55 percent of dialysis patients and 34 percent of staff are carriers of hepatitis virus B. Of those infected, 70 percent of patients and 15 percent of staff develop an anicteric hepatitis (9). Depression and rapid mood swings are recurring or chronic problems and may be related in part to electrolyte changes and other physiologic changes and in part to the psychic stress of ESRD. Barnes (9) quotes studies indicating that as many as 11 to 18 percent of deaths on dialysis may result from progressive dialysis encephalopathy. This may be caused by excessive aluminum in the central nervous system, which can result from aluminum hydroxide used to bind phosphates in the intestine or even from aluminum in the water supply.

Family-related problems occur frequently. Sometimes there is a reversal of dependency relations between spouses. Patients must restrict their diet and fluid intake. Females are frequently anovulatory and develop amenorrhea. Many males are impotent (59 percent at Mt. Zion Hospital). Women, especially, have self-image problems due to surgical scars from parathyroidectomies, splenectomies, sometimes nephrectomies, and transplant surgery (64). Levy reported on a study of 15 children in six families in which psychological assessment revealed that all 15 were clinically depressed and showed decreased academic achievement and some psychomotor disorders (43). He also reported that children whose parents were dialysed in centers rather than at home did better and were able to see the parent as more normal.

Serious dependence-independence conflicts are reported by several authors (4,25,43). Patients who had been very independent initially were forced to depend on other people and machines. Those who had always been dependent tended to regress and become extremely passive, refusing to participate in their care, attempt to work, etc. Levy reports that staff, who are also under constant strain of working with very ill, irritable, depressed patients, often use the power differential to meet their own emotional needs and may contribute to forcing people to be even more dependent (43). It is a rare patient and family who are knowledgeable enough to overcome this.

A study on suicide by Abram, Moore, and Westerfield (1971) is reported in Levy (43). That study indicates that the rate of suicide by direct action is similar among patients with ESRD to the rate among persons with other chronic diseases—seven times greater than the rate for the general population. If one includes "indirect" suicide (e. g., that caused by ignoring dietary limits, fluid overload, etc.), the rate is considerably greater.

Finally, cadaver transplants present another problem. Patients often anticipate holiday weekends with joy, since the highway death toll presents them with a chance for a better life. Then they feel guilty for wishing for another person's death. For the patients who do not obtain a kidney, there is a "Christmas eve, no Christmas morning" syndrome of disappointment and depression. Kidney transplantation is still high-risk surgery. It also requires immunosuppression, with many complications, for the rest of the person's life. Physicians, themselves, when suffering from ESRD almost never opt for kidney transplants (43), and one physician has described the agonies associated with treatment (15).

Rettig reports that one of the major disappointments and cost contributing factors of the ESRD program is that quality of life has remained poor (64). At this time, there are few solutions to this. As older and sicker patients (e.g., diabetics) are put on dialysis, this problem is apt to worsen. Yet, in most centers, potential and current patients are not routinely given an option of not starting or of terminating treatment.

Heart Transplants

There are a number of problems that all cardiac transplant patients must deal with after surgery. After discharge from the hospital, each patient must make frequent clinic visits, stay on a special diet, maintain a good weight, and get regular but moderate exercise. Most important, patients must accustom themselves to a life-long dose of immunosuppressant drugs to prevent rejection of the transplant. Artificial heart recipients would not encounter all of these problems, but their quality of life maybe severely impaired by sequelae (aftereffects) of surgery, many of which may be unforeseen.

The family of the cardiac transplant patient must also make adjustments. It is sometimes difficult for patients and their families to adjust to the new roles in which they find themselves. The sick role of the patient is no longer appropriate or desirable after transplantation, but some patients find it difficult to give up. Other potential problems include insecurities regarding self-image, guilt feelings over the burden placed on family or society, and severe depression triggered by their new status as a heart transplant patient. Of those patients who survive more than a year, 90 percent have been rehabilitated. For some, this implies a return to previous employment; for others, it means an active life as students, homemakers, or retirees (19).

It has been possible to rehabilitate the majority of Stanford's surviving cardiac transplant patients, in part because of the stringent patient selection criteria which Stanford applies, and in part because Stanford works intensively with a small number of patients. * Medical criteria include the presence of end-stage heart disease, absence of systemic disease, and minimal secondary organ damage. The psychosocial criteria include a stable work history, a history of good medical compliance, a supportive family, and a reasonable expectation that additional life will be gained by transplantation. Patients undergo extensive evaluation for psychological problems that would preclude good rehabilitation. The fact that recipients are very carefully selected and are attended closely by Stanford staff before, during, and after surgery appears crucial for the success of the Stanford program.

Problems of a Nuclear= Powered Heart

As mentioned earlier, Federal funding for research on a nuclear device has been ended—but many researchers still believe that it is preferable to other potential sources of power and continue

*Rehabilitation following heart transplantation is defined as "restoration of physical and psychosocial capacity to a level at which the patient has the options to return to employment or to an activity of choice" **(73).**

to cite it as an alternative. One drawback to the pneumatic systems that are currently being used in clinical assist devices and experimental replacement devices is that the patient or experimental animal is literally tethered to a source of compressed air. The associated noise and lack of mobility would surely have profound psychological effects on the patient were such a device to be used over a prolonged period. An additional major drawback is the risk of infection along the track of the tubing passing through the patient's chest wall.

The risk of infection is also a serious drawback to electrically powered systems that depend on percutaneous electrical leads, but is avoided by chemical batteries that can be recharged transcutaneously. Reliability, bulk, and other physical limitations are other problems with electrical and battery systems that remain to be satisfactorily resolved.

The most advanced nuclear system depends on the principle of heat generation by radioactive decay. The heat powers a miniature gas/vapor engine, which in turn drives a blood pump. Of several isotopes that might have been selected, the isotope Pu-238 with a half-life of 87 years has been used most extensively. The design requires the system to respond to physiological demands; the waste heat of the energy source must be dissipated from and by the body, and the radiation exposure must be "tolerable."

The normal heart produces some 1.5 to 4 watts of mechanical pumping power. (These power levels are over 10,000 times higher than those required for cardiac pacemaking.) Given a system of 10-percent efficiency, approximately 50 watts of energy must be produced, and 45 watts of waste heat must be continuously rejected to minimize a resultant rise of body temperature.* The proposal for the use of radioisotopes in such devices arose when the concept of "maximal permissible dose" was prevalent. This theory, postulating that there was a dose of radiation below which there was no detectable adverse biological effect, is now discredited (49).

*Current thermal engines use 25 watts of heat and have efficiencies of 13 percent or more **(30).**

Pu-238 was chosen as a power source on the basis of its short half-life, relatively low radiation, containment technology, and costs. It is an alpha-particle emitter that also has a spontaneous fission half-life of 4.9×10^{10} years, which is a source of neutron and gamma radiation. Its decay scheme is complex and results in the buildup of plutonium-236 (Pu-236), which in turn decays to emit energetic gamma. All this makes shielding the most serious problem; shielding requirements need to be determined experimentally.

A Pu-238 heat source and shielded capsule sufficient to produce 52 watts, as reported by NHLBI in 1972, was found to produce 2.7 rads per hour measured at the capsule surface and 0.6 millirem per hour measured 1 meter from the surface. Simple calculations indicate that the patient would be exposed to 23,652 rads in 1 year. The radiation dose for a spouse sharing the same bed for 8 hours per night 1 meter distant would be 1.752 rads in 1 year. To indicate the magnitude of these exposures, it should be noted that natural background radiation is about 100 millirem per year—the doubling dose of genetic mutation is estimated to fall in the range of 70 to 200 rem, and exposure of the U.S. population to 5 additional rem per 30 years could cause 3,000 to 15,000 cancer deaths annually (depending on the assumptions made in the calculation).

Discussion

From the information presented above, it can be seen that in the case of kidney and cardiac transplant patients, there exist definite barriers to posttransplant rehabilitation. Although the greatest medical problem for these patients—the host immune response to the implanted organ—would not occur in artificial heart recipients because the implanted organ would be completely artificial, the psychosocial barriers to posttransplant rehabilitation are numerous. While many dialysis and cardiac transplant patients have been able to return to work and lead active lives, many more have had substantial difficulty in doing so. If recipients of the artificial heart fare no better than recipients of heart or kidney transplants, then the claims regarding their

potential for health and economic productivity will ring false.

It also should be noted that the artificial heart will generate its own set of problems for patients. Psychological stress may characterize recipients who have difficulty coping with their total reliance on an implanted machine for life. The inconvenience and anxiety related to recharging batteries, the potential for sudden mechanical or electrical failure leading to death, or risks of radiation would clearly reduce the quality of life. The costs of implantation and continuing medical care could cause financial problems that would make adjustment harder and induce guilt in recipients over depleting family resources. How well patients deal with these problems will be determined by individual attitudes—and these will be shaped to some extent by how the rest of society receives the innovation, as well as by general concerns over our growing dependence on technology. Because so many factors affect the patient's ability to recover from implantation, adequate counseling and psychiatric services should be a part of preimplantation and postimplantation procedures. To the greatest extent possible, the decision regarding implantation should actively involve the patient so as to ensure the highest quality of life possible.

SOCIAL BENEFITS

The development of emergency and temporary devices (such as the intra-aortic balloon pump) en route to the artificial heart is a technological benefit of the artificial heart program. Similarly, the successful fabrication of biomaterials may help in the development of other artificial organs, making the research expenses incurred in the development of the artificial heart less overwhelming. In the following discussion, an effort is made to describe and estimate the social benefits that may result from a successful implantation program. The focus is on two of the most publicized potential benefits: 1) the potential gain in years of life that may result among recipients of the device, and 2) the potential for artificial heart recipients to return to an active productive life.

Extension of Life

In the foregoing discussion of economic aspects of the artificial heart program, it was noted that there has already been a substantial investment in R&D and that the costs of clinical application can be expected to be enormous. What will be the return on this investment? The 1969 Ad Hoc Task Force on Cardiac Replacement (1), while providing an estimate of the number of prospective recipients which still appears today to be a realistic one, made no effort to predict the success of replacement or how long a recipient might expect to live. However, the members of the 1973 Artificial Heart Assessment Panel (51) did make such an effort. This panel assumed at the outset that the artificial heart would be perfect—i.e., that the instrument would not fail, that there would be no deaths associated with its surgical implantation, and that all deaths from heart failure would be prevented for the subsequent 10 years. These unlikely assumptions led to equally unlikely calculations that the lo-year mortality of recipients would be substantially less than that of members of the general population of equal age. Thus, in the 10-year period following artificial heart implantation in a cohort of 1,000 60-year-olds, the panel estimated that there would be 135 deaths —from cancer, stroke, and other conditions to which we all are subject, but not from heart disease. The 10-year mortality for 1,000 60-year-olds in the general population, as reflected in the U.S. Vital Statistics at that time, was 330, more than twice that predicted for artificial heart recipients.

Though it appears that the estimates by the 1973 panel were unduly optimistic, there is no way of knowing exactly how large an increase in life expectancy among artificial heart recipients can be reasonably anticipated. If a device of high

reliability can be achieved, if the operation turns out to be technically no more difficult than a heart transplant, and if major complications such as hemorrhage and thromboembolic phenomena are infrequent, it is possible that the life expectancy of a recipient might be similar to that of other patients who have undergone successful heart surgery of equal magnitude (e.g., CABG patients). If, on the other hand, instrument reliability is as large a problem as some fear, and if there are frequent and serious clinical complications, the life expectancy of a recipient might more nearly approximate that of other patients undergoing major medical and surgical interventions (e.g., recipients of heart transplants, patients with implanted pacemakers, patients suffering from ESRD on hemodialysis, or recipients of kidney transplants). The recipient of an artificial heart would not be subject to many of the unique difficulties encountered by these other groups, but it is not unreasonable to anticipate that they may encounter difficulties of equal magnitude.

With full appreciation of the uncertainties involved, we make "best case" and'' worst case" assumptions that are described below. From these assumptions and from relevant life tables, we calculate the potential impact of an artificial heart on the life expectancy of a randomly selected member of the general population of a given age, and its impact on the life expectancy of a member of the general public of a given age who is destined to suffer death from ischemic heart disease (IHD) sometime in the future.

We have limited the analysis to potential recipients between the ages of 25 and 64. For our "best case," we have assumed that approximately one-sixth of patients dying of IHD will be candidates for artificial heart replacement (see table 6). * We also assume (see table 7) that 15 percent of recipients between the ages of 25 and 34 will die at the time of surgery or in the following year (to these recipients we assign no added years of life); we assume that an additional 30 percent will die between the ages of 35 and 44, 30 percent more will die between the ages of 45 and 54, and the remaining 25 percent will die between the ages of 55 and 64. We make parallel assumptions for recipients aged 35 to 44, 45 to 54, and 55 to 64 (see table 7).

*See discussion above on the pool of potential recipients.

Table 6.—Fraction of Those With IHD in Each Age Interval That Gets the Device—Best and Worst Case

Best case		Worst case	
Age	Fraction	Age	Fraction
0-4	0	0-4	0
5-14	0	5-14	0
15-24	0	15-24	0
25-34	1/6	25-34	1/12
35-44	1/6	35-44	1/12
45-54	1/6	45-54	1/12
55-64	1/6	55-64	1/12
65-74	0	65-74	0
75-84	0	75-84	0
85 or more	0	85 or more	0

SOURCE Calculations by A, Whittemore with the assistance of G Kelly, 1980

For our "worst case, " we assume that only one-twelfth of patients dying of IHD will become candidates for replacement (see table 6). We also assume higher initial mortality and a higher failure rate (see table 8). Other observers or investigators may choose to revise our calculations using different sets of assumptions.

Calculations:

Using the age-specific death rates due to all causes (see table **9)** and to IHD (see table 10), we first estimated the "net" distribution of time to occurrence of IHD. This is the distribution in the hypothetical absence of all other causes of death. We also estimated the net distribution of time to death from other causes, in the absence of death due to IHD. These computations were done as described in Chiang (18).

To describe the impact of an artificial heart device, we assumed that a fraction γ_i, of those who develop IHD in their i^{th} age interval gets the device (see table 6). We also supposed that a proportion r_{ji} of those getting the device in interval j dies due to complications associated with the device in a subsequent interval i, i >= j. The proportions r_{ji} are shown in table 7 (best case) and **8** (worst case).

We then computed a new net distribution of death due to IHD, assuming that the device was available. Note that in this case an individual can die in the ith age interval from IHD in two ways: Either the person developed IHD and fails to receive the device, or the person dies as a re-

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Table 7.—Proportion of Those Obtaining the Device That Dies Due to Device Failure at Subsequent Ages—Best Case

	Age at which device was obtained						
Age at which device failed	o-4	5-14	15-24	25-34	35-44	45-54	55-64
0-4	0	0	0	0	0	0	0
5-14	o	0	0	0	0	0	0
15-24	O	0	0	0	0	0	0
25-34	O	0	0	0.15	0	0	0
35-44	o	0	0	0.3	0.2	0	0
45-54	0	0	0	0.3	0.35	0.25	0
55-64	0	0	0	0.25	0.35	0.4	0.3
65-74	0	0	0	0	0.1	0.3	0.45
75-84	0	0	0	0	0	0.05	0.25
850 or more	0	0	0	0	0	0	0

SOURCE: Estimates by D. Lubeck and J. P. Bunker 1980.

Table 8.—Proportion of Those Obtaining the Device That Dies Due to Device Failure at Subsequent Ages—Worst Case

	Age at which device was obtained						
Age at which device failed	O-4	5-14	15-24	25-34	35-44	45-54	55-64
0-4	o	0	0	0	0	0	0
5-14	o	0	0	0	0	0	0
15-24	0	0	0	0	0	0	0
25-34		o	0	0.3	0	0	
35-44	:	o	0	0.6	0.4	0	0
45-54	0	0	0	0.1	0.6	0.5	0
55-64	0	0	0	0	0	0.5	0.6
65-74	0	0	0	0	0	0	0.4
75-84	0	0	0	0	0	0	0
85 or more	0	0	0	0	0	0	0

SOURCE: Estimates by D.Lubeck and J. P. Bunker, 1980.

Table 9.—Age-Specific Death Rates Due to All Causes, 1977

Age	Death rate
0-4	0.000688
5-14	0.000346
15-24	0.001171
25-34	0.001362
35-44	0.002475
45-54	0.006207
55-64	0.01434
65-74	0.030556
75-84	0.071819
85 or more	0.147259

SOURCE: Mont/rly *Vita/StafisficsReport* (Hyattsville,Md.: National Center for Health Statistics).

Table 10.—Age-Specific Death Rates Due to IHD,1977

Age	Death rate
o-4	0
5-14	0
15-24	0.000004
25-34	0.000042
35-44	0.000384
45-54	0.001683
55-64	0.004665
65-74	0.011164
75-84	0.028895
85 or more	0.064201

SOURCE: *Monthly Vita/ Statistics Report* (Hyattsville,Md.: National Canter for Health Statistics)

suit of complications associated with a device received in a previous interval j<= i. The probability of the first event is $f_i(1-\pi_i)$, where f_i is the net probability of the occurrence of IHD in interval i. The probability of the second event is:

$$\sum_{j<=i} f_j \pi_j r_{ji}$$

Thus, the new net probability f'_i of death due to IHD in interval i is:

$$f'_i = f_i(1-\pi_i) + \sum_{j<=i} f_j \pi_j r_{ji}$$

This new net distribution, together with the net distribution for time to death due to other causes, yielded a single distribution for time to death, as described by Chiang (18), in the event that the device is available. By comparing this distribution with current death rates, we calculated the increase in life expectancy due to the device that might be enjoyed by a randomly chosen individual in the U.S. population. The gains in life expectancy for individuals who ultimately develop IHD were also calculated. These gains are shown in tables 11 and 12.

From table 11, we see that under our "best case" assumptions, a randomly chosen 25-year-old gains 0.0966 of a year (or approximately 35 days) in life expectancy from the availability of an artificial heart; under our "worst case" assumptions, the gain is reduced to 0.0218 of a year (or about a week). The gain in life expectancy will accrue only to those 25-year-olds

Table 11.—Increase in Life Expectancy in Years for Randomil Selected individuals of Specified Ages Who May or May Not Develop IHD– Best and Worst Case

Best case		Worst case	
Age	Increase in life expectancy	Age	Increase in life expectancy
0-4	0.096	0-4	0.0214
5-14	0.0963	5-14	0.02146
15-24	0.0966	15-24	0.0215
25-34	0.0966	25-34	0.0218
35-44	0.0963	35-44	0.02096
45-54	0.0804	45-54	0.0151
55-64	0.0306	55-64	0.0011
65-74a	– 0.0602	65-74a	–0.019
75-84a	– 0.0137	75-84	0.0
85 or more	0.0	85 or more	0.0

aNegative values in persons over age 65 reflect the impact on this age group of patients who have received the artificial heart prior to age 65 and who bear the added risk of death due to complications or disease.

SOURCE: Calculations by A. Whlttemore with the assistance of G. Kelly, 1960.

Table 12.—Increase in Life Expectancy in Years for individuals of Specified Ages Who Will Ultimately Develop IHD-Best and Worst Case

Best case		Worst case	
Age	Increase in life expectancy	Age	Increase in life expectancy
0-4	0.6025	0-4	0.1343
5-14	0.6029	5-14	0.1344
15-24	0.6033	15-24	0.1345
25-34	0.6049	25-34	0.1348
35-44	0.59085	35-44	0.1285
45-54	0.4925	45-54	0.0925
55-64	0.1935	55-64	0.007
65-74a	– 0.4925	65-74a	– 0.1342
75-84a	-0.1430	75-84	0.0
85 or more	0.0	85 or more	0.0

aNegative values in persons over age 65 reflect the impact on this age group of patients who have received the artificial heart prior to age 65 and who bear the added risk of death due to complications or disease.

SOURCE: Calculations by A. Whittemore with the assistance of G. Kelly, 1980.

destined to develop IHD. As shown in table 12, the calculated increase in life expectancy for these individuals, 0.6049 year (best case) and 0.1348 year (worst case), is considerably greater than that for randomly selected 25-year-olds.

Comparable calculations are presented in tables 11 and 12 for individuals in 10-year age groups up to the age of 84. It should be noted that at older ages the gain in life expectancy becomes smaller, because older individuals have a much shorter period of time in which to become candidates. It also should be noted that there is a decrease in average life expectancy among persons over age 65. This results from the inclusion in this age group over time of individuals who received an artificial heart prior to reaching age 65 (individuals age 65 and over are themselves ineligible for the device). Such persons have a lower than average life expectancy because of the risk of future complications associated with the artificial heart, so their inclusion in this age group decreases the overall average.

In order to arrive at the average population increase, the increase in life expectancy for a randomly selected individual in each age group is multiplied by the fraction of the population in that age group and summed. Under the "best case" conditions, the average increase is 0.0697 year (25 days). Under the "worst case" conditions, the average increase is 0.0106 year (4

days). For those individuals destined to develop IHD, the average increase for the "best case" is 0.4478 year (163 days). The average increase for the "worst case" is 0.0926 year (34 days).

Return to Work

In order to estimate the possible effect of artificial heart surgery on return to work, we reviewed the experience of patients undergoing hemodialysis and CABG surgery. The findings from the studies cited below indicate that each intervention has considerable impact on the occupational situation of patients, especially in the case of older individuals. The findings also cast some doubt on the early predictions that the artificial heart will be economically beneficial to society by returning large numbers of individuals from their sickbeds to gainful activity.

Hemodialysis Patients

Though several authors discuss the return-to-work issue for dialysis patients, all say that the data are not very good (9,25,43,64). However, McKegeny, cited in Levy (43), reported that many dialysis patients could return to work part time (20 hours per week), but do not do so because they would lose all benefits for their treatment. McKegney also comments that dialysis patients are still weak and anemic and have intercurrent illnesses. Katz and Capron (39) report better experience for dialysis patients in the United Kingdom. There, 66 percent of patients are on home dialysis, which can be done during sleep at night. Sixty-five percent of those patients return to work full time.

CABG Patients

A study of 893 men at a median time of 14 months after CABG surgery was reported by Rimm, et al. (65). Seventy-six of the men were retired at the time of surgery, leaving 817 men of all ages and occupational groups in the study. The following six occupational groups were defined: 1) professionals; 2) administrators, managers, officials, and providers; 3) clerical and sales workers; 4) skilled workers, foremen, and tradesmen; 5) metal processors, machinery workers and factory workers; 6) semiskilled and unskilled workers.

Of the 817 men working before surgery, 52.9 percent stayed in the same occupational group, 31.1 percent changed occupational group, and 17 percent retired. In the subgroup of 510 patients less than 55 years of age who were working before surgery, 56.1 percent stayed in the same occupational group, 32.5 percent changed occupational group, and 11.4 percent retired. In the subgroup of patients 55 years of age and older, 47.6 percent stayed in the same occupational group, 26 percent changed occupational group, and 26.4 percent retired. In the latter age group, persons in occupational groups 4, 5, and 6 had only a 60- to 70-percent overall return to work. The authors found that the observed retirement rate in the study population was 7.5 times that of a comparable U.S. male population for those 35 to 54 years of age and 11.3 times that for those who were older.

Crosby, et al. (24) found that at an average of 18 months after surgery for left main coronary artery disease, 62 percent of 70 patients returned to work; 32 percent retired on disability; and 6 percent who were able to work chose to retire. Information disaggregated by age categories was not presented in this study.

A Toronto study (75) assessed the proximity to retirement age and its effects on employment patterns after CABG surgery. Of 329 patients (men and women), 178 were employed before surgery (54 percent). Of these 178, 122 were under 55 years of age, and 56 were older. Two years after surgery, 81 percent of those under age 55 and 75 percent of those over age 55 were employed. Overall, 79 percent of the 178 patients returned to work.

Finally, in a review of the effect of CABG surgery on work status, McIntosh and Garcia (47) mention a study of patients at Emory University. The effect of CABG surgery on patients' work status was less than its effect on their exercise tolerance levels. Its effect on work status depended on individual economic considerations (especially retirement provisions). Although 90 percent of the patients observed at

Emory had symptomatic improvement, only 50 percent returned to work after surgery.

The evidence with regard to positive occupational rehabilitation as a result of CABG surgery is conflicting. Studies of patients in randomized trials show a lesser return to work for surgical patients than for medical patients (59). It seems that even if the procedure is successful, many patients seize the opportunity to retire, which is at that time socially acceptable and legitimate. Factors that influence this choice are the duration of postoperative recovery and the availability of compensation or retirement benefits.

Artificial Heart Recipients

Thus, we have several proxies on which to base estimates of probability of return to work after artificial heart implantation. The percentage of cardiac transplant patients who return to work is 20 to 25 percent (62). Because cardiac transplantation leaves the recipient prone to infections and rejection from the body's immune system, however, we believe that this percentage is lower than might be expected among recipients of an artificial heart.

Patients with coronary artery disease amenable to surgery are often in much better medical condition than those who would be receiving an artificial heart. Thus, we believe that the return-to-work figures for the coronary bypass group represent an upper limit. From the study by Rimm, et al. (65), we note a return-to-work percentage of 70 to 80 percent for CABG patients under age 55 and from so to 70 percent for CABG patients between age 55 and 65. We also note an approximate percentage of 60 percent of persons with advanced kidney disease on home dialysis who are able to maintain a normal working condition.

Thus, we would suggest as the overall percentage of previously employed artificial heart recipients who might return to work after surgery a lower limit of 20 percent (based on the experience of heart transplant patients) and an upper limit of 60 percent (based on the experience of CABG patients).

SOCIAL COSTS

A comparison of the costs of the artificial heart must include not only the charges to the consumer, but future economic effects on society as a whole. Below we discuss four prominent issues that arise in connection with proposed development of an artificial heart: 1) increased social expenditures, 2) distributional issues, 3) social costs of a nuclear device, and 4) opportunity costs.

Increased Social Expenditures

The extent of increased costs to society will depend on the quality of the artificial heart in clinical application. A highly effective device could increase the productivity of midcareer recipients and greatly benefit society. An inadequate device, however, would mean, in addition to losses in productivity, the loss to society of its investment in R&D, and charges for implantation, continuing medical care, welfare and rehabilitation programs.

The potential burden on social security and other retirement programs is related not only to the reliability and effectiveness of the artificial heart, but also to the quality of rehabilitation and the desire of recipients to return to active lives. The experience of cardiac transplant patients emphasizes the importance of psychosocial and economic motivation for complete rehabilitation. Likewise, the rapid diffusion of CABG surgery, with its disappointing return-to-work figures, suggests that considerable planning—with an eye toward comprehensive treatment, counseling and restricted development—should precede clinical application of the artificial heart to ensure the best possible results.

Given the large number of patients who might benefit from artificial heart surgery, the cost could run into the billions, as predicted by Sapolsky in 1978 (70). Yuki Nosé, of the Cleveland Clinic, has expressed the opinion that societal costs will equal those of present dialysis

payments by medicare (which now exceed $1 billion).

From our own assumptions, if the average cost of artificial heart surgery is $28,000 and 33,600 implantations are done each year, the yearly aggregate cost for the surgery alone would be $941 million (see table 2). Added to the cost of surgery are continuing care costs—estimated at $2,000 per patient per year—which will increase incrementally as the number of procedures (and patients) accrues.

Using our figures (which are conservative estimates) for the cost of implantation and the pool of recipients, and applying these continuing care costs ($2,000 per patient per year) to the survival rates of heart transplant patients at Stanford (i.e., 70-percent survival for the first year and 5-percent attrition each succeeding year, or 50-percent survival through 5 years) yields the 5-year cost projections in table 13. As can be seen in that table, first year costs for 33,600 implantations at $28,000 per procedure would be about $941 million. Second year costs would be $941 million for another 33,600 implantations (at $28,000 per procedure) plus maintenance costs of about $47 million for the 23,520 survivors (at $2,000 per survivor), or a total of about $988 million. Third year costs would be $941 million for another 33,600 implantations plus maintenance costs of about $91 million for the survivors, or a total of about $1,032 million. Fourth and fifth year costs, calculated similarly, would be about $1,072 million and $1,109 million, respectively.

Even at these cost levels and projected patient pools, the artificial heart (when distributed on a large scale) will incur costs equivalent to present dialysis payments within 1 year. If the implantation turns out to be more costly, then the program will rapidly approach $2 billion annually. The decision to finance hemodialysis and the recent recommendation to finance cardiac transplants through medicare indicates that the costs of artificial heart implantation will probably be federally financed. If the experience of hemodialysis is typical of procedures supported by public funds, then we can expect a progression toward more relaxed patient selection criteria for and widespread availability of the artificial heart. Previously excluded candidates would thus be included. As the recipient group is expanded, and more resources are invested, the marginal quality-of-life improvements and longevity improvements will lessen.

Though the impact of the artificial heart on total population growth may be small, an increase in the proportion of older citizens may necessitate increased expenditures by social security and medicare to cover rehabilitation and early retirement. The present burden on social security due to our expanding elderly population is already well documented and of fiscal concern. The burden of increased social security expenditures will fall on all taxpayers. If recipients of the device are substantially more productive than they would have been without it, costs of the program maybe made up through increased tax revenue, as was predicted in the 1966 Hittman Report (35). Therefore, the development of a strong comprehensive rehabilitation program is crucial if the artificial heart is designed for large-scale distribution.

Table 13.—Projected 5-Year Sequence of Total National Expenditures on Artificial Heart Implantation and Patient Maintenance (dollars in millions)

	First year	Second year	Third year	Fourth year	Fifth year
Implantation charges	$940.80	$940.80	$ 940.80	$ 940.80	$ 940.80
Maintenance					
Year 1	—	47.04	47.04	47.04	47.04
Year2	—	—	43.68	43.68	43.68
Year3	—	—	—	40.32	40.32
Year4	—	—	—		36.96
Total costs	$940.80	$987.84	$1,031	.52 $1,071.84	$1,108.80

SOURCE: D. Lubeck and J. P. Bunker, 19S0. See text for assumptions.

Distributional Issues

In the experimental years of the artificial heart program, strict patient selection criteria (similar to those for cardiac transplantation) would limit distribution and reimbursement problems. However, as the procedure becomes established for therapy, and medical criteria are relaxed, there will be fewer clinical reasons to deny the artificial heart to an individual able to benefit from it. Thus, financial considerations will gain in significance.

Even the most conservative estimates of the cost of the artificial heart project an amount that would be a severe burden on many families. Insurance companies, particularly in the early years of the artificial heart's availability, maybe unwilling to shoulder the high costs of such an innovative treatment, just as they have been in the case of cardiac transplants. Yet, in recent years, Americans more and more have come to see access to available modes of health care as a basic right that should not depend on one's ability to pay. The decision to cover hemodialysis under medicare is the most notable illustration. In the case of the artificial heart, the demand for public financing would be strengthened by the fact that the device came into existence only because citizens' tax dollars financed its development.

If artificial hearts do become available, the Federal Government will be faced with a serious dilemma—either to deny many citizens access to a device sponsored by a Government research program or to embark on a subsidization plan that could run into billions of dollars annually. Patient selection criteria and the mode of reimbursement will be the policy components that establish the scope and equity of artificial heart distribution. The challenge will be to design economically realistic financing and allocation arrangements that will not ration life on the basis of the value of individual members to society.

Social Costs of a Nuclear Device

The social cost of a plutonium-fueled artificial heart relates to the associated environmental and social hazards. Plutonium is an extremely toxic material. Each capsule (containing about 50 g of Pu-238) is the equivalent of many millions of lethal doses to a human being. From manufacture through transportation and storage to implantation, the materials would have to be protected from accidents and thefts that might result in breach of the capsule and release of the Pu-238 into the environment. After a patient's death, the material would have to be quickly recovered and returned to the Government. Since the basic premise of developing a device is that the device will be widely distributed, it follows that the safeguards associated with a nuclear power source would also be widely applied. The problems that could arise under conditions of unexpected use, theft, terrorism, or accident are dramatized by the estimate (with a very wide range of variability) that if the 50 g of Pu-238 in the artificial heart were to be distributed as an ideally aerosolized particle, that particle would be the equivalent of 1.7 billion doses of, lung cancer (26).

In addition to these risks, another consideration is the capital costs. At the current price of Pu-238 ($1,000 per g), each device (containing 50 g of Pu-238) would cost $50,000 for fuel alone. At 50,000 devices per year, the initial costs for fuel alone would be $2.5 billion. If this were financed at lo-percent simple interest per year, the finance charge would be $250 million per year. These costs would be added on to the other costs previously mentioned.

Opportunity Costs

In considering the costs of the artificial heart program, one must also take into account potential gains that might have accrued from other social expenditures precluded by the primacy of artificial heart development. Although spending on one project does not automatically preclude spending on another program, the development and promotion of an artificial heart is likely to reemphasize the importance of alternative approaches to the treatment of heart disease, as well as increase social costs.

As noted earlier, distribution of the artificial heart may proportionately raise social expenditures financed through medicare and social secu-

rity, so funds will have to be diverted from other programs. This will be especially true if social security, in the future, is partially financed from general funds. There are additional potential tradeoffs in the area of biomedical research. Thus, for example, the question may be asked whether the research funds that support the training of new heart surgeons and technicians will deter or undermine research on heart disease prevention or other forms of treating cardiovascular disease.

Completion of the artificial heart, as noted in the introduction to this case study, was projected to occur long before an effective cardiac disease prevention program. However, today there are several prevention programs that hold the potential for reaching more people and at less cost than the artificial heart. The alternative of cardiac disease prevention is discussed in more detail below.

CARDIAC DISEASE PREVENTION

A perspective on heart replacement can be obtained by comparing replacement with alternative programs that have the same criteria of effectiveness (i.e., increased life expectancy) and represent present investments for the future. One alternative is to try to prevent the occurrence of heart disease by altering individual and institutional patterns of behavior.

Independent risk factors that contribute to premature cardiac disease are elevated serum cholesterol, cigarette smoking, and high blood pressure. Much of the evidence supporting the importance of these factors stems from the Framingham study, epidemiological studies that compare affluent, technology-based societies with those less affluent, and collaborating evidence from population studies.

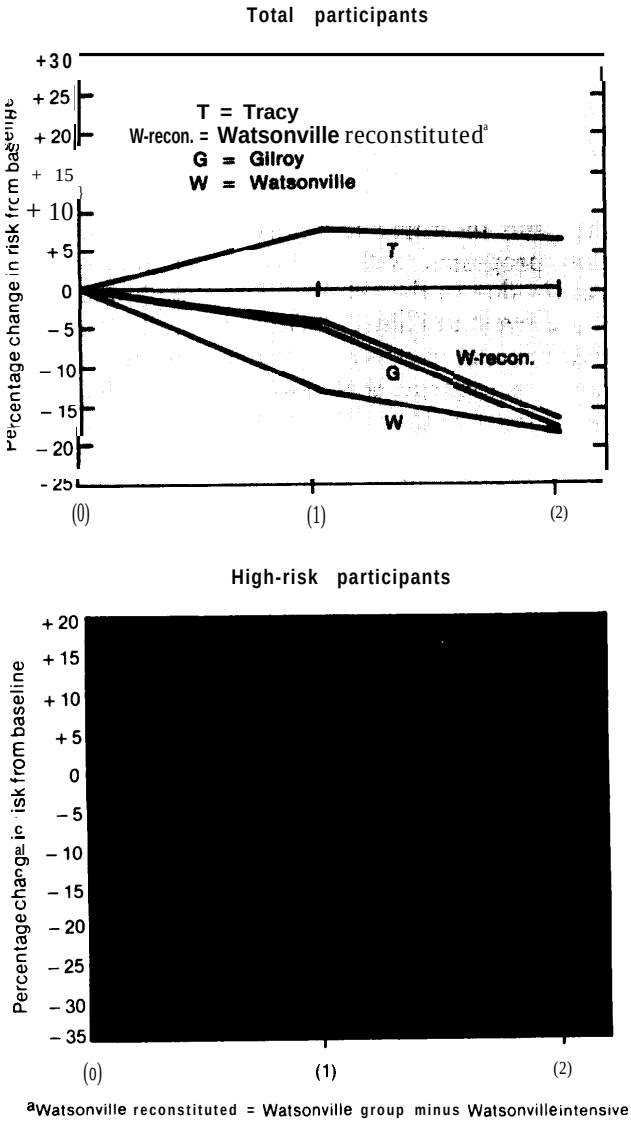
The evidence establishing a constellation of risk factors related to coronary heart disease (CHD) led NHLBI in 1970 to fund several decade-long, community-based clinical trials designed to develop methods of risk reduction applicable to home, work, and community environments. The Stanford Heart Disease Prevention Program (SHDPP) was initiated in 1971 as part of this NHLBI research.

To estimate the potential effectiveness of modifying risk factors in preventing CHD in the U.S. population, we have chosen to look at the results of the SHDPP Three Community Education Study. This study, completed in 1975, has demonstrated increased community awareness of heart disease factors, changes in targeted behavior (reductions in smoking and cholesterol levels), and a decrease in risk factors. It indicates the great potential of prevention in reducing death from CHD, though conclusive evidence on whether a population or an individual will experience an actual decline in mortality is not yet available (more information about the SHDPP study is presented in app. D).

Three comparable communities were selected for the study: one control town (Tracy) and two experimental towns (Gilroy and Watsonville). The experimental towns received health education through a mass campaign (radio, TV, newspaper, and direct mail) over 2 years. Additionally, high-risk individuals (those in the top quartile) were exposed to two different treatments: media education only (Gilroy) and a media program enriched by face-to-face instruction (Watsonville intensive instruction). Data were gathered through regular interviews of a random sample of 35- to 59-year-old men and women, which measured knowledge about behavior related to CHD, as well as daily dietary and smoking habits. After 2 years of intervention, a decrease in overall risks of 23 to 28 percent was realized in the two experimental communities. There was a small increase in risk in the control group (27). Figure 2 summarizes the changes in risk for each community.

In order to determine the effectiveness of risk reductions, one must evaluate the frequency of CHD risk factors in the population and the degree of concentration within categories. Data

Figure 2.— Percentage Change in Risk of CHD After 1 and 2 Years of Health Education in Various Study Groups From Three Communities



[a]Watsonville reconstituted = Watsonville group minus Watsonville intensive instruction group
[b]Watsonville randomized control = Watsonville high-risk group minus Watsonvine Intensive Instruct Ion group
[c]Watsonville intensive Instruct Ion = Watsonville high-risk intensive group

SOURCE: Stanford Heart Disease Prevention Program, Stanford, Calif.

from the National Cooperative Pooling Project (2) indicate that 8 percent of 30- to 59-year-old men have three or more risk factors elevated; 30 percent have two or more factors elevated; 45 percent have one; and 17 percent have no elevated risk factors. By combining risk factors with their associated mortality, one finds that if only 50 percent of those individuals in the category of having two or more elevated factors participated in a similar prevention program, there would be a 23-percent reduction in new cases of CHD. If all individuals in that category were to participate, there would be as much as a 45-percent reduction in new cases.

Expected life extensions due to a directed prevention program can only be very generally estimated until more data are collected. Tsai used multiple decrement and cause-related life tables to estimate the improvement in life expectancy due to a reduction in new cases of CHD (76). He found that if CHD is reduced by 20 percent, a member of the total population gains an average of 1.26 years of life. However, if a 50-percent reduction in CHD is achieved (the potential of a national program directed towards those with two or more elevated risk factors), the average gain is 3.7 years of life. These estimates far surpass any overall population life expectancy increases that might result from the availability of the artificial heart. *

In order to estimate the costs of a similar prevention program on a national scale, we have evaluated the media and personnel costs of the SHDPP Three Community Education Study (27). A summary of program costs over the period from 1972 to 1975 is given in table 14. The total cost for the three media campaigns for the two experimental communities was $515,477. SHDPP has estimated that a similar program on a national level would cost approximately $1.5 billion.

We also reviewed another comprehensive community program in Finland. The North Karelia Project was carried out from 1972 to 1977 in the county of North Karelia, an area of Finland with exceptionally high CHD rates (60). The objective was to reduce the mortality and morbidity of CHD among middle-aged men (ages 25 to 59), through reduction of smoking, serum cholesterol levels, and elevated blood pressure. More than 10,000 subjects were studied, with a participation rate of around 90 percent. Program activities were integrated with

* See extension of life estimates discussed earlier.

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Table 14.—SHDPP Expenses by Media Campaign

	Campaign 1	Campaign 2	Campaign 3	Total
Media costs	$120,150	$ 74,246	$33,930	$228,326
Personnel	87,960	57,958	69,153	215,071
Surveys and data	33,243	20,639	18,198	72,080
Total	$241,353	$152,843	$121,281	$515,477
Number of months				
Average/month	$8,045	$12,737	$10,107	$9,546

SOURCE: Stanford Heart Disease Prevention Program, Stanford, Cal if,

existing social service structures and the media. The activities involved providing health services, advising individuals on changing personal behavior, advising communities on environmental changes, training personnel, and providing media information.

The results were evaluated by examining independent population samples at the start and at the end of the project in North Karelia and in a matched reference county. An overall mean net reduction of 17.4 percent among all males was observed in the estimated CHD risk in North Karelia. Changes in individual risk factors were greatest for hypertension (down 43.5 percent), followed by smoking (down 9.8 percent), cholesterol levels (down 4.1 percent), and blood pressure (down 3.6 percent). However, although risk factors were reduced in North Karelia, the change in mortality was statistically the same in both communities in the study.

A precise economic comparison of the cost effectiveness of preventive programs v. the artificial heart is not feasible until more information is available on the costs, risks, and benefits of both approaches. The effectiveness of the artificial heart is still not known, since such a device is not yet ready for clinical testing. By the same token, the effectiveness of the SHDPP in reducing cardiac deaths remains to be documented, though the program is effective in reducing certain CHD-related risk factors. An array of alternative programs (including heart transplants) provides the context for decisions regarding public funding of disease treatment.

The two programs—cardiac disease treatment and prevention—could coexist in a beneficial manner, as many of our consultants noted. John Watson, of NHLBI, mentioned that the opportunity and incentive to improve cardiac prevention programs will continue, despite the advances due to the artificial heart. Yuki Nosé, of the Cleveland Clinic, mentioned that expensive treatment programs may also lead to better diagnostic equipment that may reverse or halt disease progression for those not improved by cardiac disease prevention. The distribution and cost problems of the artificial heart might be reduced if a prevention program were judiciously used to reduce CHD to a level where those persons in need of an artificial heart would have easier access to it. Cost containment or private health insurance program incentives could be used to encourage this.

The data necessary for an economic evaluation of the two programs that would compare the average cost per patient and the marginal cost per additional patient are not available. However, we can make some general statements. If the cost of an artificial heart will not decline incrementally because it is a specialized technology and production competition will not be realized, then no cost savings will be realized through mass production. In contrast, the types of prevention programs undergoing clinical trials now will have decreasing programing costs as educational programs are standardized and distributed more widely in classrooms and through the mass media.

In assessing the cost effectiveness of a technology still in the R&D stage, one must consider the chances of attaining the desired effects and at what level. There are still great uncertainties to be resolved in the development of the artificial heart (e.g., biomaterials and energy sources) and in prevention programs (e. g., their effect on reduction of cardiac deaths). A useful way to

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.

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.

APPENDIX A: THE ARTIFICIAL CARDIAC PACEMAKER

by Thomas Preston

The first totally implantable cardiac pacemaker was implanted in Sweden in **1959.** This was followed by the development of implantable pacers by three companies in the United States in 1960 (17,37,78). Although animal investigations predicted a problem with electrodes (rising excitation threshold), this problem was considered manageable, and there were widespread forecasts for a 5-year pacemaker longevity. The 5-year longevity prediction was based on battery capacity and calculated discharge rate. The first commercially available pacemakers were designed with the pulse generator and leads as one inseparable unit, i.e., there was no design allowance for replacement of the pulse generator alone, without disturbing the electrical connections (leads) to the heart. Although some investigators voiced caution about heightened expectations (78), in general there was optimism that a 5-year pacemaker was at hand (17,37).

Risks

The major risk of permanent pacing—operation mortality—initially was about 7.5 to 10 percent due to the requirement for thoracotomy and epicardial electrode placement. That risk was deemed acceptable because of the poor prognosis of untreated patients and the dramatic relief of successfully paced patients (see the section below on benefits). Other risks that also usually meant pacemaker system failure included infection at any part of the operative area (from epicardium with myocardial abscess to infection around the pulse generator) and dehiscence (bursting) of the pulse generator. In its worst manifestation, the patient had an acquired abscess with draining fistula. These complications were relatively common initially (5 to 10 percent), but not unexpected. Improved surgical technique solved most of these problems.

Complications peculiar to pacemakers that were relatively or totally unanticipated are discussed below.

- Wire (lead) ***break.*** Fatigue of the metal leads resulted in premature system failure at a high rate, such that this was the primary limiting factor for the first few years of permanent pacing. The solution of this problem required engineering analysis of fracture points and modes, followed by multiple design changes. Although lead breaks still occur, this complication was controlled to an acceptable incidence over a period of 6 to 7 years.
- ***High threshold of cardiac excitation.*** As noted above, animal testing revealed this complication, which was medically unique to this technology. The biotechnical factors involved were not well worked out until about 1967, and electrode evolution pertaining to this feature still continues. In the first 5 years of permanent pacemakers, at least 10 percent of system failures were from this cause.
- ***Battery*** failure. The predicted battery longevity did not materialize until about 1975 because of defects with the batteries and current shunting due to structural defects within the pulse generator. Excluding all other failure modes, pulse generator longevity as limited by battery exhaustion is listed in table A-1. The dramatic increase in pacemaker longevity from 1975 to 1979 reflects the development of a new technology battery (lithium).
- ***"Runaway" pacemakers.*** Rarely, but dramatically, pulse generators can fail with an accelerated rate (up to 800 impulses per minute). In some cases, this complication was fatal. Although design changes have made this complication quite rare, it still occurs (e.g., recall of American Pacemaker Co., June 1979).
- ***Electromagnetic interference.*** Interference caused by extrinsic noncardiac signals can alter pacemaker output signals. This problem was greatly magnified by creation of the sensing ("on demand") pacemaker, which must sense cardiac signals but reject all other electrical signals. This complication (incorrect sensing) still occurs with approximately 5 percent of implanted units.
- ***Competition with natural heart beats.*** Although this complication was anticipated, it was not

Table A. 1.—Pacemaker Longevity Excluding Causes of Failure Other Than Battery Exhaustion

Year pacemaker implanted	Longevity (50%)
1961	6to 12 months
1965	12 months
1970	24 months
1975	42 months
1979	10 years (est.)

SOURCES: S. Furman and D. Escher, *Principles and Techniques of Cardiac Pacing (New* York: Harper and Row, 1970); and M. Bilitch, "Performance of Cardiac Pacemaker Pulse Generators," *PACE* 2:259, *1979,*

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considered serious (78). Although it is an infrequent occurrence, pacemaker stimulation during the vulnerable period of a preceding natural beat can precipitate ventricular fibrillation and death (59). proper sensing of natural depolarizations (demand function) precludes this complication, but inadequate sensing still occurs with about 5 percent of implanted units.

- Surgical ***inexperience.*** The use of a prosthetic device posed new problems for surgeons. Many complications—e. g., incorrect connection of pulse generator to leads, improper positioning of electrodes or pulse generator—are related to expertise in this particular operation. Furthermore, normally functioning pacemaker systems have been removed, because the surgeon and/or cardiologist did not understand the proper functioning of the system. Trauma to the device through mishandling still occurs in the hands of the inexperienced.
- ***Manufacturing errors.***
- ***Sudden failure,*** From specifications and performance of the batteries (for the first 15 years, virtually all batteries were the same type), the expected failure mode was a slow but detectable change in pacer rate. Unexpected, sudden failure without prior detected rate change has occurred and still does occur for a number of reasons (lead break, component failure, short circuit, etc.). For a patient who is pacemaker dependent, this mode of failure produces syncope (temporary suspension of circulation) or death. Sudden unexpected failure is now uncommon (approximately 1 in **50** to 100 pulse generators), but occurred with 5 percent or more of pulse generators for the first 10 years of permanent pacing.

Benefits

- ***Survival.*** There never has been a well-controlled study comparing survival of patients with and without pacemakers, presumably because of the apparent immediate and dramatic success of pacemakers. Analysis of survival benefit has always been made by comparison of prepacing and postpacing groups. Patients with complete (or intermittent) heart block and syncopal episodes have a l-year mortality of **50** percent **(29,36),** whereas similar patients who are paced have a 2-year survival of 70 to 80 percent (68). Survival analysis of patients paced for reasons other than complete heart block is virtually impossible, as no "natural history" data exist for other conditions. The diagnoses of partial blocks and sick sinus syndrome appear to be a consequence of pacing, as these disorders were relatively unknown prior to permanent pacing, and investigations into these disorders probably resulted from the innovation of a treatment for them. Thus, the availability of pacemakers led to investigation into nonheart block causes of syncope. Pacemaker therapy was applied to other presumed causes of syncope as soon as a cause and effect relationship seemed to exist, as in sick sinus syndrome. The universally acknowledged success of pacing for heart block led to an uncritical extension of the therapy to patients with "preheart block" EKG patterns, and sinus node dysfunction. Consequently, there are no data (even uncontrolled) by which to judge the effect of pacing on survival in these groups of patients. Some believe that the widespread use of pacing for preheart block syndromes does not increase survival **(46).** Of all patients receiving pacemakers, about 55 to 60 percent now survive 5 years (31).
- ***Treatment of symptomatic complete heart block.*** The advent of pacing led to legendary tales of how the moribund rose to walk. For those who remember the plight of patients with symptomatic complete heart block, the benefit in terms of decreased syncopal episodes and increased activity level is beyond question. For patients with other maladies, however, the benefits are more questionable. Most patients with light-headedness spells, or true syncope, and without evidence of heart block or sinus arrest associated with syncope, end up with pacemakers. Many are not improved.
- ***Treatment of symptomatic bradycardia,*** Availability of pacing has created the option of adjunct therapy (e. g., large doses of propranolol) with pacing to avoid symptomatic bradycardia.
- ***Treatment*** of ***tachyrhythmias.*** An unanticipated new use of pacemakers is in treatment of tachyrhythmias, using overdrive or interruption techniques. This accounts for less than 1 percent of all permanent pacing.

Capital Investment

- ***Initial cost.*** The cost of hospitalization and hardware was estimated easily and adequately at the time of initiation of this technology.
- ***Followup care.*** The unanticipated complications of systems failures meant greater than estimated followup costs. I know of no studies in 1960-61 estimating followup costs. Although the anticipation was for 3 to 5 years of fault-free system performance, during the first 3 years of pacing, the average system longevity was about 6 months. Some pa-

tients had in excess of 15 operations (some more than 20) in 3 to 5 years, most of them thoracotomy (surgical incision of the chest wall). During the next 5 years, the average system failure (any failure requiring surgical correction, e.g., wire break, displacement of catheter, generator failure) was about 1 in 12 months of pacing (or greater).

Exclusive of complications requiring hospitalization/operative repair, modern followup methods now cost from $100 to $1,600 per year, depending on the mode of followup. Office visits (minimum, EKG; maximum, detailed pacemaker analysis at a "pacemaker clinic") vary from **2** to **6** years in routine followup. Electronic monitoring (even interrogation of implanted units) has become widespread in this country during the last 10 years. It can be done directly (with the patient present at a clinic) or indirectly by telephone, with or without automatic computer analysis. The availability of such monitoring has made it mandatory in the minds of most physicians, as this represents the "best" means of followup. Indeed, there is now a whole ancillary industry in this area. The artificial heart, for which monitoring would be even more necessary, will undoubtedly have more advanced forms of electronic monitoring. Third-party payers (Blue Cross/Blue Shield, medicare) now pay **$30** per telephone call for pacemaker monitoring. Many patients are monitored weekly (there is a scale of allowable calls, as a function of the age of the pacemaker), meaning a monitoring cost of $1,560 per year. I anticipate a minimum of one call per week for artificial heart patients.

- ***Indirect cost (or gains),*** There are no data on return to employment of paced patients, but for those who were incapacitated from symptomatic complete heart block, there is a return to normal existence (excluding other limitations). Thus, for the group heavily dependent on pacemakers, there would appear to be a large net gain in return to gainful employment. For others, the result is less evident. To the degree that a patient is restored to normal function, there should be an economic gain. The countereffect, as seen with coronary artery surgery, of legitimation of illness and retirement may also be present. I know of no data on this subject.

APPENDIX B: CARDIAC TRANSPLANT COSTS

Table B-1.–Cardiac Transplant Hospitalization Costs, 1969.75

	Days	Insurance	Grant	Professional fees	Blood credit	Drug credit	Written off	Total	Cost/day
Year 1. . . .	1,788	$87,923.57	$ 493,385.20	$3,109.53	$ 325.00	–	$36,485.96	$ 621,229.26	$347.44
Year2. . . .	841	144,561.47	129,443.33	150.00	485.00	—	31,318.31	305,958.11	363.80
Year 3. . . .	942	267,677.56	106,956.45	1,001.47	712.98	$ 18.40	796.85	377,163.71	400.39
Year4. . . .	869	122,962.32	235,811.89	10,062.83	73.05	—	44,380.79	413,290.88	475.59
Year5. . . .	922	360,158.01	186,294.45	12,177.33	834.00	211.84	326.17	560,001.80	607.38
Year 6. . . .	198	—	101,887.09	3,444.00	–	–	—	69,489.65	534.54
Total. . .	5,560	$983,282.93	$1,253,778.41	$29,945.16	$2,430.03	$230.24	$113,308.08		
Percent of total	—	4170	*53%*	1 %	—	—	*5%*		
Average/ person . .	69	$12,139.29	$15,478.75	$369.69	$30.00	$2.84	$1,398.87	$2,382,974.85 100%	$428.59
Average/ transplant	65	$11,433.52	$14,578.82	$348.20	$28.26	$2.68	$1,317.54	$29,419.44 $27,709.01	$426..37 $426.29

SOURCE: Stanford Cardiac Transplantation Program, Stanford, Cal if.

Table B-2.–Cardiac Transplant Outpatient Costs, 1969-75

	Visits	Insurance	Grant	Professional fees	Blood credit	Drug credit	Written off	Total	Cost/visit
Year 1. . . .	466	$ 580.10	$ 19,768.80	$1,095.00	–	–		$21,443.90	$46.02
Year2. . . .	224	854.50	12,802.89	1,170.00	—	—	$ 877.95	15,705.34	70.11
Year 3. . . .	112	74.85	8,434.04	–			—	8,508.59	75.97
Year4. . . .	468	7,774.72	41,269.30	632.64			851.95	50,528.61	107.97
Year5. . . .	523	5,970.50	48,956.87	1,620.90	—	—	—	56,548.27	108.12
Year 6. . . .	110	—	9,306.10	786.00	—	—	—	10,092.10	91.75
Total. . .	1,903	$15,254.67	$140,538.00	$5,304.54	–	–	$1,729.90	$162,827.11	$85.56
Percent of total	—	*9%*	*86%*	*4%*	—	—	1 %	100%	—
Average/ person . .	23	$188.33	$1,735.00	$65.49	–	–	$21.36	$2,010.21	$87.40
Average/ transplant	22	$177.38	$1,634.16	$61.68	–	–	$20.12	$1,905.34	$86.61

SOURCE: Stanford Cardiac Transplantation Program, Stanford, Cal if,

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PROJECT TITLE	L INVESTIGATOR	NIS	L	DBP	BUDGET DATES	D] COST	I ECT COST	To?) L	F Y
2 13426-99 PENNSYLVANIA STATE LEFT BYPASS	PIERCE, S INFARCTION		7605		09-01-78 08-31-79	1S2,725			78
5 13738-08 IV OF UTAH CITY uTAH CA ASSIST DEVICES AND	WI J HEARTS	AL T I ERI	7800		09-01-78 03-31-79		175,s00	510,331	78
5 CLINIC HOSPITAL		T ERI	7800		06-76 04-01-78 05-79 05-31-79		30,263		
5 CHILDREN'S HOSPITAL BOSTON MASSACHUSETTS LEFT AND COMPOSITE PROSTHESIS	F		7800		01-77 01-01-79 12-79 12-31-79	25,000			79
5 STATE HERSHEY AND	PIERCE, S ARTIFICIAL HEART		7900		02-80 02-29-80			251,833	
2 UTAH SALT CITY UTAH BALLOON IN ANIMALS	J		7901	HBP	05-79 05-01-79				79
5 OF A TRANSFER SYSTEM	E		7900	HBP	03-s0 03-31-80			82,160	79
5 INSTITUTE OF FLOW IN ARTERIAL BIFURCATIONS	C FORBES, JR	E	7800	HBP	12-77 11-80 12-01-78 11-30-79	51,140	20,4S2	71,622	79

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05-08-79

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE GRANTS ACTIVE AS OF 05-08-79
ARRANGED IN PROGRAM ORDER
DEVICES AND TECHNOLOGY BRANCH

GRANT NUMBER / INSTITUTION / PROJECT TITLE	PRINCIPAL INVESTIGATOR	ADMINISTRATOR	NHLAC	DBP	PROJ DATES	BUDGET DATES	DIRECT COST	INDIRECT COST	TOTAL AWARDED	FY
5 R01 HL22329-02 SINAI HOSPITAL OF DETROIT DETROIT MICHIGAN ACTIVE PROSTHETIC MYOCARDIUM: EFFECTS ON LV FUNCTION	KANTROWITZ, ADRIAN	ALTIERI	7900	HBP	04-78 03-80	04-01-79 03-31-80	65,997	40,984	106,981	79
R01 HL22661-01 UNIVERSITY OF UTAH SALT LAKE CITY UTAH CHRONIC TOTAL CARDIOPULMONARY MECHANICAL SUBSTITUTION	MORTENSEN, J D	ALTIERI	7805	HBP	09-78 08-81	09-01-78 08-31-79	141,230	74,295	215,525	78
R01 HL23941-01 COLUMBIA UNIVERSITY NEW YORK NEW YORK SIMPLE CARDIAC ASSIST (TALV) DEVICES IN MAN	DOBELLE, WILLIAM H	ALTIERI	7901	HBP	04-79 03-82	04-01-79 03-31-80	85,000	26,546	111,546	79
		RECORD COUNT SUPPLEMENTS					1,211,610	525,592	,737,202	
R01 HL11418-09 PENNSYLVANIA STATE UNIVERSITY UNIVERSITY PARK PENNSYLVANIA POLYDIAMINOPHOSPHAZENES	ALLCOCK, HARRY R	PITLICK	78[illegible]	HBQ	06-76 05-79	06-01-78 05-31-79	33.24	[illegible]4	[illegible]5.58[illegible]	7
R01 HL12839-10 WASHINGTON UNIVERSITY SAINT LOUIS MISSOURI BLOOD CELLS: PHYSICAL PROPERTIES, STRUCTURE AND FUNCTION	SUTERA, SALVATORE P	PITLICK	7810	HBQ	12-78 11-81	12-01-78 11-30-79	150,272	71,127	22 ,399	79
5 P01 HL15195-04 CASE WESTERN RESERVE UNIVERSITY CLEVELAND OHIO PROGRAM PROJECT IN BIOLOGICAL MATERIALS	WALTON, ALAN G	PITLICK	7800	HBQ	06-74 05-80	06-01-78 05-31-80	349,357	164,811	514,168	7
5 R01 HL16921-05 UNIVERSITY OF UTAH SALT LAKE CITY UTAH SYNTHETIC HYDROGELS AS BLOOD TOLERABLE MATERIALS	ANDRADE, JOSEPH	PITLICK	78[illegible]	HBQ	06-77 05-80	06-01-78 05-31-79	78,285	34,617	112,902	7

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NATIONAL HEART, LUNG, AND BLOOD INSTITUTE GRANTS ACTIVE AS OF 05-027 9
ARRANGED IN PROGRAM ORDER
DEVICES AND TECHNOLOGY BRANCH

GRANT NUMBER / INSTITUTION / PROJECT TITLE	PRINCIPAL INVESTIGATOR	ADMINISTRATOR NHLAC	DBP	PROJ DATES	BUDGET DATES	DIRECT COST	INDIRECT COST	TOTAL AWARDED	F Y
1 R01 HL20236-01A1 UNIVERSITY OF TENN CENTER HEALTH SCIEN MEMPHIS TENNESSEE SURFACE-ACTIVE ANTITHROMBOTIC AGENTS FOR PROSTHESES	QUINTANA, RONALD P	PITLICK 7901	HBQ	04-79 03-82	04-01-79 03-31-80	53,283	13,892	67,175	79
5 R01 HL22455-02 UNIVERSITY OF MIAMI CORAL GABLES FLORIDA PLATELET CONCENTRATION IN THE MARGINAL LAYER	ECKSTEIN, EUGENE C	PITLICK 7900	HBQ	04-78 03-80	04-01-79 03-31-20	23,745	15,572	39,317	79
5 R01 HL22585-02 UNIVERSITY OF SOUTH FLORIDA TAMPA FLORIDA PLASMA PROTEINS ADSORBED TO ARTIFICIAL ORGANS	CHUANG, HANSON Y	PITLICK 7900	HBQ	04-73 03-81	04-01-79 03-31-80	33,257	15,874	49,131	79
1 R01 HL22587-01 UNIVERSITY OF SOUTH FLORIDA TAMPA FLORIDA ENDOTHELIAL LININGS FOR ARTIFICIAL ORGANS	MASON, REGINALD G, J R	PITLICK 7810	HEQ	12-78 11-81	12-01-78 11-30-79	46,468	20,<94	66,962	79
5 R01 HL22627-02 UNIVERSITY OF SOUTH FLORIDA TAMPA FLORIDA ANINHIBITOR OF PLATELET ADHESION TO ARTIFICIAL ORGANS	MASON, REGINALD G, JR	PITLICK 7s00	HBQ	01-78 12-80	01-01-79 12-31-79	2S,609	14,659	43,268	7?
1 R01 HL23016-01A1 BAYLOR COLLEGE OF MEDICINE HOUSTON TEXAS RESPONSE OF CULTURED ENDOTHELIAL CELLS TO FLOW	ESKIN, SUZANNE G	PITLICK 7901	HBQ	05-79 04-81	05-01-79 24-30-&O	39,672	13,734	53,406	79
1 R01 HL23274-01 UNIVERSITY OF CALIFORNIA BERKELEY BERKELEY CALIFORNIA HEMOLYSIS INDUCED BY SHEAR FLOW	WILLIAMS, MICHAEL C "	PITLICK 7810	HBQ	12-78 11-31	12-01-78 ?1-30-79	47,251	14,648	61,899	79
1 R01 HL23288-01 UNIVERSITY OF MICHIGAN ANN ARBOR MICHIGAN POLYORGANOPHOSPHAZENES; MOLECULAR MOTION & THROMBOSIS	BARENBERG, SUMNER A	PITLICK 7810	HBQ	12-78 11-81	12-01-78 11-30-79	45,550	28,083	73,633	79

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05-08-79

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE GRANTS ACTIVE AS OF 05-08-79
ARRANGED IN PROGRAM ORDER
DEVICES AND TECHNOLOGY BRANCH

GRANT NUMBER / INSTITUTION / PROJECT TITLE	PRINCIPAL INVESTIGATOR	ADMINISTRATOR / NHLAC	DBP	PROJ DATES	BUDGET DATES	DIRECT COST	INDIRECT COST	TOTAL AWARDED	FY
2 RO1 HL 12715-10 DUKE UNIVERSITY DURHAM NORTH CAROLINA DYNAMIC CARDIOVASCULAR MEASUREMENT USING ULTRASOUND	THURSTON E, FREDRICK L.	POWELL 7&05	HBU	09-73 08-81	09-01-78 08-31-79	159,592	86,755	246,377	78
2 RO1 HL 14645-08 UNIVERSITY OF WASHINGTON SEATTLE WASHINGTON BLOOD FLOW MEASUREMENT BY ULTRASONIC CATHETER TIP METHOD	MARTIN, ROY W	POWELL 7810	HBU	12-78 11-81	12-01-72 11-31-79	71,573	20,977	92,450	79
5 RO1 HL 14785-07 PROVIDENCE MEDICAL CENTER SEATTLE WASHINGTON ULTRASONIC SCATTERING STUDY FOR TISSUE CHARACTERIZATION	REID, JOHN M	POWELL 7800	HBU	06-76 05-79	95-01-78 05-31-79	68,173	9,723	77,896	78
2 RO1 HL 15016-07 UNIVERSITY OF ROCHESTER ROCHESTER NEW YORK NEW CONCEPTS IN CARDIAC ULTRASOUND TECHNOLOGY	GRAMIAK, RAYMOND	POWELL 7805	HBU	09-78 08-81	09-01-78 08-31-79	93,496	31,318	124,814	78
2 RO1 HL 16487-06 INTERMOUNTAIN HEALTH CARE SALT LAKE CITY UTAH COMPUTER CONTROLLED TWO-DIMENSIONAL ECHOCARDIOGRAPHY	PRYOR, T ALLAN	POWELL 7901	HBU	05-79 04-82	05-01-79 04-30-80	53,010	7,919	60,929	79
5 RO1 HL 16759-06 UNIVERSITY OF WASHINGTON SEATTLE WASHINGTON ULTRASONIC MEASUREMENT OF CARDIAC GEOMETRY AND FLOW	MORITZ, WILLIAM E	POWELL 79C0	HBU	05-77 04-80	05-01-79 04-30-80	39,200	0	0	79
5 RO1 HL 17604-03 SRI INTERNATIONAL MENLO PARK CALIFORNIA WEARABLE BLOOD PRESSURE AND ECG RECORDING SYSTEM	WEAVER, CHARLES S	ALTIERI 7700	HBU	05-75 IC-79	05-01-77 10-31-79	119,159	63,685	182,844	77
5 RO1 HL 13968-03 STATE UNIVERSITY OF NEW YORK AT BUFFALO BUFFALO NEW YORK COMPUTER TECHNOLOGY FOR TRANSAXIAL TOMOGRAPHY	HERMAN, GABOR T	POWELL 7800	HBU	05-76 05-79	05-01-78 05-31-79	113,312	52,113	165,425	78

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DIVISION OF HEART AND VASCULAR DISEASES

OF THE

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

BETHESDA, mARYLAND 20205

RESEARCH AND DEVELOPMENT CONTRACTS

NOVEMBER, 1980

U.S. **DEPARTMENT OF HEALTH AND HUMAN SERVICES**
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF **HEALTH**

POWER SOURCES - ELECTRICAL Dr. Altieri

Dr. John Moise
Aerojet Liquid Rocket
Aerojet-General Corp.
POB 13222, Dpt 2150
Sacramento, CA 95813
(916) 355-2018
NO1-HV-7-2971
Implantable Electrohydraulic Left Heart Assist Devices
Expired: 9/29/80

Dr. Robert Jarvik
University of Utah
Inst. Biomedical Eng
Salt Lake City, UT 84112
(801) 581-6991
NO1-HV-7-2975
Reversing ElectroHydraulic Energy Converter for Assist Devices
Expired: 9/29/80

Dr. Peer H. Portner
Andros, Inc.
2332 Fourth St
Berkeley, CA 94710
(415) 849-1377
NO1-HV-4-2914
Implantable Controlled Solenoid LVAs
Expired: 9/2/80

Mr. Jack Chambers
Gould Measuremnt Syst
Statham Instr Div
2230 Statham Blvd
Oxnard, CA 93030
(805) 487-8511
NO1-HV-8-2916
Electrical Energy Converter for Heart Assist Devices
Expired: 9/18/80

Mr. Victor Poirier
Thermo Electron Corp
101 Firat Ave
Waltham, MA 02154
(617) 890-8700
NO1-HV-7-2976
Electrical Energy Convertera for Heart Assist Devices
Expired: 9/29/80

Power SOURCES - RENEWAL

Dr. Altieri

Dr. John Moise
Aerojet Liquid Rocket
Aerojet Gen Corp
POB 13222, Dpt 2150
Sacramento, CA 95813
(916) 355-2018
NO1-HV-9-2909
Develop, Evaluate Stirling Cycle Conversion System
FY 80: $893,176

Mr. Richard P. Johnston
Univ of Washington
100 Sprout Rd.
Richland, WA 99352
(509) 375-3176
NO1-HV-9-2908
Develop, Evaluate Codified Cycle Engine
FY 80: $792,306

CIRCULATORY ASSIST & ARTIFICIAL HEART DEVICES PROGRAM

Dr. Jeffrey L. Peters
Inst for Biomed Eng
University of Utah
Bldg 518
Salt Lake City, UT84112
(801) 261-3141
Single & Biventricular Cannulae Circulatory Support
5 RO1 HL 23279-02

Dr. William S. Pierce
Hershey Medical Ctr
Penn State University
500 University Dr
Hershey, PA 17033
(717) 534-8328
Development and Evaluation of an Artificial Heart
2 RO1 HL 20356-04

Dr. William S. Pierce
Hershey Medical Ctr
Penn State University
500 University Dr
Hershey, PA 17033
(717) 534-8328
Left Ventricular Bypass for Myocardial Infarction
5 RO1 HL 13426-11

Dr. Andreas F. Von Recum
College of Eng
Clemson University
301 Rhodes Eng Blvd
Clemson, SC 29631
(803) 656-3052
Healing of Intestinal Mucosa to a Penetrating Conduit
5 RO1 HL 23646-02

Dr. Andreas F. Von Recum
College of Eng
Clemson University
301 Rhodes Eng Blvd
Clemson, SC 29631
(803) 656-3052
Treated Percutaneous Implants
1 RO1 HL 25438-01

Dr. Frederick J. Walburn
Dept of Medicine
Henry Ford Hospital
2799 W. Grand Blvd
Detroit, MI 48202
(313) 876-3221
Pulsatile Flow,Separation in Branching Tubes
1 R23 HL 25839-01

Dr. Stanley A. Briller
Allegheny-Singe r
Research Corp
320 E. North Ave
Pittsburgh, PA 15212
(412) 237-3146
Syntactic Pattern Analysis of 24-hr Helter Records
1 RO1 HL 26066-01

Dr. K.B.Chandran
Materials Eng Div
University of Iowa
College of Eng
Iowa City, IA 52242
(319) 353-4192
Pulsatile Flow Dynamics of Prosthetic Heart Valves
1 RO1 HL 26269-01

Dr. Richard E. Clark
Dept of Surgery
Washington University
4960 Audubon Ave
St Louis, MO 63110
(314) 454-3457
Advanced Cardiac Valvular and Vascular Prostheses
5 RO1 HL 13803-07

Dr. Herman L. Falsetti
Dept of Internal Med
University Hospitals
Iowa City, IA 52242
(319) 356-3412
Fluid Mechanics of Heart Valve Prostheses
3 RO1 HL 20829-03S1

Dr. Leslie A. Geddes
Purdue University
Biomedical Eng Ctr
W. Lafayette, IN 47907
(317) 494-6151 X212
An Automatic Implantable Blood Pressure Controller
1 RO1 HL 25746-01

Dr. Howard C. Hughes
College of Medicine
Penn State University
Hershey, PA 17033
(717) 534-8328
Elimination of Reoperative Cardiac Pacemaker Surgery
5 RO1 HL 13988-09

Dr. Janice L. Jones
School of Medicine
Case Western Univ
2119 Abington Rd
Cleveland, OH 44106
(216) 368-3487
Defibrillator Waveshape Optimization
5 ROl HL 24606-02

Dr. Raymond J. Kiraly
Dept.of Art. Organs
Cleveland Clinic
9500 Euclid Ave
Cleveland, OH 44106
(216) 444-2470
Hexsyn Leaflet Valve
1 RO1 HL 25689-01

THERAPEUTIC INSTRUMENTATION & DEVICES PROGRAM

Dr. Victor Parsonnet
Dept of Surgery
Newark Beth Israel
Medical Center
Newark, NJ 07112
(201) 926-7330
Extending the Life of Implanted Pacemakers
5 RO1 HL 15247-07

Dr. Victor Parsonnet
Newark Beth Israel
Medical Center
201 Lyons Ave
Newark, NJ 07112
(201) 926-7330
Simulation of Pacemaker - ECG Interactions
5 RO1 HL 24567-02

Dr. Lester R. Sauvage
Providence Med Center
528 18th Avenue
Seattle, WA
(206)326-5891
Prosthesis for Aorotocoronary Bypass
2 RO1 HL 18644-04AI

Dr. John C. Schuder
Surgery Department
Univ of Missouri
Columbia,MO 65212
(314) 882-8068
Waveform Dependency in Defibrillating 100 KG Calves
5 RO1 HL 18040-06

Dr. John C. Schuder
Surgery Department
Univ of Missouri
Columbia, MO 65212
(314) 882-8068
Development of Automatic Implanted Defibrillator
5 RO1 HL 21674-03

Dr. William F. Walker
Dept Mech Eng
Rice University
PO BOX 1892
Houston, TX 77001
(713) 527-8101 x3549
Cavitation Phenomena Near Prosthetic Devices
5 RO1 HL 17821-04

Dr. Herbert L. Abrams
Dept of Radiology
Petr Bent Brighm Hosp
721 Huntington Ave
Boston, MA 02115
(617) 734-8000 X2542
Cineangiographic Studies of the Cardiovascular System
5 RO1 HL 20895-05

Dr. Donald W. Baker
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Univ of Washington
Seattle, WA 98195
(206) 543-6832
Noninvasive Cardiovascular Measurements
5 PO1 HL 07293-18

Dr. Dana H. Ballard
Dept of Computer Sci
Univ of Rochester
Rochester, NY 14627
(716) 275-3772
Anatomical Modela in Computer-Aided Image Analysis
5 R23 HL 21253-03

Dr. Joe D. Bourland
Biomedical Eng Ctr
Purdue University
West Lafayette, IN 47907
(317) 494-6151
Cardiac Output from the Pneumocardiogram
5 RO1 HL 22321-03

Dr. Ruben D.Bunag
University of Kansas
Medical Center
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Kansas City, Kansas66103
(913) 588-7507
Non-Invasive Blood Pressure Measurement
5 RO1 HL 22854-02

Dr. David A. Chesler
Physics Research Lab
Mass General Hospital
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(617) 726-3805
Gated Imaging with the MGH X-Ray Camera
5 RO1 HL 20274-03

Dr. B. Neil Cuffin
Mass Inst of Tech
170 Albany St
Cambridge, MA 02139
(617) 253-5562
Accuracy of Electric & Magnetic heart Measurements
2 R23 HL 24645-02

Dr. Cornelis J. Drost
Dept Physiology
NY State Vet College
Cornell University
Ithaca, NY 14853
(607) 256-2121
Accurate Transcutaneous Doppler Bloodflow Monitoring
5 RO1 HL 19019-05

Dr. Nancy C. Flowers
U of Louisville
School of Medicine
323 E. Chestnut St
Louisville, KY 40202
(502) 589-4668
Recording & Analysis of Low Level Cardiac Signals
2 RO1 HL 19768-04

Dr. Fred K. Forster
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Dept of Mech Eng
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(206) 543-4910
Fluid Dynamic-Ultrasonic Aspects of Blood Turbulence
1 R23 HL 26706-01

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(317) 494-6151 x321
Indirect Mean Blood Pressure
2 RO1 HL 18947-03

Dr. Edward A. Geiser
Dept. of Medicine
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Gainesville, FL 32610
(904) 392-3481
3-D Analysis of Ventricular Contractile Performance
1 R23 HL 25621-01

Dr. Don P. Giddens
Sch of Aerospace Eng
Georgia Inst of Tech
Atlanta, GA 30332
(404) 894-3044
Hemodynamics of Normal and Diseased Carotid Arteries
5 RO1 HL 22635-02

Dr. Raymond Gramiak
Univ of Rochester"
601 Elmwood Ave
Rochester, NY 14642
(716) 275-2625
New Concepts in Cardiac Ultrasound Technology
5 RO1 HL 15016-09

Dr. Craig J. Hartley
Dept of Medicine
The Methodist Hosp
6516 Bertner
Houston, Tx 77030
(713) 790-3252
Ultrasonic Instrumentation for Cardiovascular Studies
5 RO1 HL 22512-03

Dr. Gabor T. Herman
Dept of Computer Sci
SUNY at Buffalo
4226 Ridge Lea
Amherst, NY 14226
(716) 831-1351
Computer Technology for Transaxial Tomography
5 RO1 HL 18968-05

Dr. Michael B. Histand
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Fort Collins, CO 80523
(303) 491-5544
Noninvasive Measurement of Cardiac Output
5 RO1 HL 22326-03

Dr. Cecil J. Hodson
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333 Cedar Street
New Haven CT 06510
(203) 432-4364
Ultrasonic Monitoring of Visceral Blood Vessels
5 RO1 HL 19791-03

Dr. Adrian Kantrowitz
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Sinai Hosp of Detroit
6767 West Outer Dr
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(313) 493-5775
Quantitating In-Series Effects in Cardiac Arrhythmias
5 RO1 HL 22274-02

Dr. Antti J. Koivo
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Purdue Univ
West Lafayette, IN47907
(317).493-9156
The Use of Microprocessors in Medical Applications
1 RO1 HL 22417-01

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(516) 246-5061
Cardiovascular NMR Zeugmatography
5 RO1 HL 19851-02

Dr. Richard L.Longini
Biotechnology Program
Carnegie-Mellon Univ
Pittsburgh, PA 15213
(412) 578-2528
An Optimal Fetal Heart Monitor
2 RO1 HL 20632-03

Dr. Roy W. Martin
Dept Anesthesiology
U of Washington
Seattle, WA
(206) 545-1883
Blood Flow Measurement by Ultrasonic Catheter Tip Method
5 RO1 HL 14645-09

Dr. William E. Moritz
Dept of Elec Eng
Univ of Washington
Seattle, WA 98195
(206) 543-6049
Ultrasonic Measurement of Cardiac Geometry and Flow
5 RO1 HL 16759-06

Dr. P. David Myerowitz
U of Wisconsin
Department of Surgery
600 Highland Ave
Madison, WI
(608) 263-5215
Noninvasive Computerized Fluoroscopic Cardiac Imaging
1 RO1 HL 26586-01

Dr. Charles P. Olinger
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Univ of Cincinnati
4305 Med Sci Bldg
Cincinnati, Ohio 45267
(513) 872-5431
Computer Aided Bioacoustic Arterial Diagnostics
5 RO1 HL 23671-02

Dr. T. Allan Pryor
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Latter-Day Saint Hosp
325 8th Ave
Salt Lake City, UT 84143
(801) 322-5761 X255
Computer Controlled Two-Dimensional Echocardiography
2 RO1 HL 16487-06

Dr. John M. Reid
Inst of Applied
Physiology & Medicine
556 18th Avenue
Seattle, WA 98122
(206) 442-734o
Ultrasonic Scattering Studies for Tissue Characterization
5 RO1 HL 24805-02

Dr. Erick L. Ritman
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Mayo Foundation
200 First St. SW
Rochester, MN 55901
(507) 284-3495
Cardiovascular and Lung Dynamics
2 POl HL 04664-20

Dr. William P. Santamore
Temple University
Philadelphia, PA
(215) 221-4724
Ventricular Interdependence
1 RO1 HL 26592-01

Dr. Richard K. Shaw
School of Medicine
Yale University
333 Cedar Street
New Haven, CT 06510
(203) 436-8259
Long Term Assessment of Flow in Vascular Grafts
5 RO1 HL 22352-02

Dr. Richard J. Spears
Dept of Cardiology
USC Schl of Medicine
2025 Zonal Ave
Los Angeles, CA 90033
(213) 226-2152
3-D Analysis of Single Plane Coronary Cineangiograms
1 R23 25272-01

DIAGNOSTIC & MEASUREMENT INSTRUMENTATION & DEVICES PROGRAM

Dr. Donald E. Strandness
Dept of Surgery
Univ of Washington
Seattle, WA 98195
(206) 543-3653
Ultrasonic Evaluation in Direct Arterisl Surgery
2 RO1 HL 20898-03

Dr. Louis E. Teichholz
Dept of Med
Pit Sinai Schl of Med
1 Gustave L Levy P1
New York, NT 10029
(212) 650-7785
Pulse-Doppler Analysis of Left Ventricular Function
1 RO1 HL 25277-01

Dr. Fredrick L. Thurstone
Biomedical Eng Dept
Duke University
Durham, NC 27706
(919) 684-6185
Dynamic Cardiovascular Measurement Using Ultrasound
5 RO1 HL 12715-12

Dr. John G. Webster
Dept. of Elec. Eng.
U of Wisconsin
1500 Johnson Dr.
Madison, WI 53706
(608) 263-1574
Portable Arrhythmia Monitor
1 RO1 HL 25691-01

Dr. Mark L. Yelderman
Dpt of Anesthesia
Stanford University
Stanford, CA 94305
(415) 497-6411
A Continuous Cardiac Output Monitor
5 RO1 HL 24798-02

BIOMATERIALS PROGRAM

Dr. Clarence P. Alfrey
Dept of Internal Hed
Methodist Hospital
6516 Bertner
Houston, TX 77030
(713) 790-2155
Effects of Physical Forces on Blood
5 RO1 HL 16938-05

Dr. Harry R. Allcock
Dept of Chemistry
Penn State Univ
University Park, PA 16802
(814) 865-3527 "
Polydiaminophosphazenes
5 RO1 HL 11418-11

Dr. Joseph D. Andrade
Dpt of Bioengineering
University of Utah
Salt Lake City, U1' 84112
(801) 581-8509
Synthetic Hydrogels as Blood Tolerable Materials
5 RO1 HL 16921-06

Dr. Joseph D. Andrade
Dpt of Bioengineering
University of Utah
Salt Lake City, UT 84112
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Albumin and Hemocompatibility
2 RO1 HL 18519-05

Dr. Joseph D. Andrade
Dpt of Bioengineering
University of Utah
Salt Lake City, UT 84112
(801) 581-8509
Blood Interactions of Triblock Polymers
5 RO1 HL 24474-02

Dr. Robert E. Apfel
Eng & Applied Sci Dpt
Yale University
New Haven, CT 06520
(203) 436-8674
Characterization of Biomaterials by Elastic Property
5 RO1 HL 22233-03

Dr. John Autian
College of Pharmacy
Univ of Tennessee
Ctr for Health Sci
Memphis, TN 38163
(901) 528-6020
Acute Toxicity Evaluation of Biomaterials
5 RO1 HL 24040-02

Dr. Sumner A. Barenberg
Dept of Chemical Eng
Univ of Michigan
Ann Arbor, Michigan 48109
(313) 764-7391
Polyorganophosphazenes ; Molecular Motion & Thrombosis
5 RO1 HL 23288-02

Dr. William E. Burkel
Dept of Anatomy
Univ of Michigan
4734 Medical Sci II
Ann Arbor, MI 48109
(313) 764-4379
Development of Cell-Lined Vascular Prostheses
3 RO1 HL 23345-02S1

Dr. Allan D. Callow
Dept of Surgery
New Eng Med Ctr Hosp
171 Harrison Ave
Boston, MA 02111
(617) 956-5596
Platelet-Fibrin Dynamics in Healing Arterial Surfaces
5 RO1 HL 24447-02

Dr. Hanson Y.K. Chuang
Dept of Pathology
University of Utah
School of Medicine
Salt Lake City, UT 84112
(801) 581-7773
Plasma Proteins Adsorbed to Artificial Organs
7 RO1 HL 25808-01

Dr. Hanson Y.K. Chuang
Dept of Pathology
University of Utah
Salt Lake City, UT 84112
(801) 581-7773
Interaction: Prothrombin, Thrombin, ATIII & Materials
1 RO1 HL 25807-01

Dr. Stusrt L. Cooper
Dept of Chem Eng
Univ of Wisconsin
1415 Johnson Dr
Madison, WI 53706
(608) 262-3641
Protein and Thrombus Deposition on Vascular Graft
5 RO1 HL 21001-03

Dr. Stuart L.Cooper
Dept of Chem Eng
Univ of Wisconsin
1415 Johnson Dr
Madison, WI 53706
(608) 262-3641
Transient Thrombotic Events at Polymeric Surfaces
5 RO1 HL 24046-02

Dr. W. Jean Dodds
Div of Lab & Research
NY St Dept of Health
Empire St Plaza
Albany, NY 12201
(518) 457-2663
Blood-Materials Interactions: The Bridge Problems
5 RO1 HL 24017-02

Dr. Robert C. Eberhart
Dept of Mech Eng
University of Texas
Eng Sci Bldg 610
Austin, TX 78712
(512) 471-7167
Analysis of Blood Trauma From Microporous Oxygenators
5 RO1 HL 19173-04

BIOMATERIALS PRO(WWbl

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Coral Gables, FL 33124
(305) 284-2442
Platelet Concentration in the Marginal Layer
2 RO1 HL 22455-03

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Dept of Surgery
University of PA
3400 Spruce St
Philadelphia, PA19104
(215) 662-2091
Platelet Function During Extracorporeal Perfusion
5 RO1 HL 19055-05

Dr. Suzanne Gaston Eskin
Dept of Surgery
Baylor College of Med
1200 Moursund
Houston, TX 77030
(713) 790-4567'
Response of Cultured Endothelial Cells to Flow
5 RO1 HL 23016-02

Dr. Evan A. Evans
Dept of Biomed Eng
Duke University
Durham, NC
(919) 684-5218
RBC Membrane Adhesion & Deformation Energies
1 RO1 HL 24796-01

Dr. John L. Glover
Purdue University
at Indianapolis
Indianapolis, IN
(317) 630-7491
Seeding of Endothelial Cells in Vascular Prostheses
1 RO1 HL 24247-O1A1

Dr. Donald E. Gregonis
University of Utah
Salt Lake City, UT
(801) 581-7899
Basic Studies on Blood-Polymer Interactions
1 RO1 HL 26469-01

Dr. Frederick Grinnell
Dept of Cell Biology
University of Texas
5323 HarryHines Blv
Dallas, TX 75235
(214) 688-2181
Blood-Material Interactions: Adsorption of Fibronectin
5 RO1 HL 24221-02

Dr. Jesse D. Hellums
Dept of Chem Eng
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Houston, TX 77001
(713) 527-3497
Effects of Physical Forces on Platelets
5 RO1 ill 18584-05

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Dept Macromolec Sci
Case Western Res Univ
University Circle
Cleveland, OH 44106
(216) 368-4186
Long Term Biodegradation of Elastomeric Biomaterials
1 RO1 HL 25239

Dr. Cornelis A. Hoeve
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Texas A&M University
College Station, TX 77843
(713) 845-3243
Guidelines for Polymers Acting as Elastin Substitutes
5 RO1 HZ 18441-03

Dr. Allan S. Hcoffman
Bioengineering Ctr
Univ of Washington
Seattle, WA 98195
(206) 543-9423
Surface Thrombogenesis Mechanisms and Prevention
5 PO1 HL 22163-03

Dr. Thomas A. Horbett
Dept of Chem Eng
Univ of Washington
Seattle, WA 98195
(206) 543-6419
Cellular Interactions with Foreign Materials
2 RO1 HL 19419-05

Dr. Ting-Cheng Hung
School of Medicine
U of Pittsburgh
Pittsburgh, PA 15261
(412) 624-5369
Study of Leukocyte Degradation Characteristics
1 RO1 HL 25814-01

Dr. Lucija Stacic Karic
Inst of Med Sciences
Pacific Medical Ctr
Clay & Webster Sts
San Francisco, CA 94120
(415) 563-2323 X2416
Extracorporeal Circulation & Protein Denaturation
5 R23 HZ 21271-03

Dr. Sung Wan Kim
School of Pharmacy
University of Utah
Skaggs Hall
Salt Lake City, UT 84112
(801) 581-6801
Initial Events in Thrombus Formation on Surfaces
5 RO1 HL 17623-07

Dr. Sung W. Kim
School of Pharmacy
University of Utah
Skaggs Hall
Salt Lake City, UT 84112
(801) 581-6801
A Novel Approach to Nonthrombogenic Polymer Surfaces
2 RO1 HL 20251-04

DEVICES AND TECHNOLOGY BRANCH

DIVISION OF HEART AND VASCULAR DISEASES

OF THE

NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

BETHESDA, MARYLAND 20205

RESEARCH AND DEVELOPMENT GRANTS

NOVEMBER, 1980

U.S. **DEPARTNENT OF HEALTH AND** HUMAN SERVICES
PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

Dr. William F. Bernhard
Childrens Hospital
Medical Center
300 Longwood Ave
Boston, MA 02115
(617) 734-6000 X3261
Evaluation of a Left Ventricular-Aortic Prosthesis
5 RO1 HL 20037-03

Dr. William F. Bernhard
Children's Hospital
Medical Center
300 Longwood Avenue
Boston, MA 02115
(617) 734-6000 X3261
Clinical Left Ventricular Bypass Studies
1 RO1 HL 25882-01

Dr. Erich E. Brueachke
St. Lukes Medical Ctr
1753 W Congresa Pk
Chicago, IL 60612
(312) 942-7083
Development of a Transcutaneous Power Transfer System
5 RO1 HL 21632-03

Dr. John E. Chimoskey
Dept of Physiology
Michigan State Univ
East Lansing, HI 48824
(517) 355-9269
Left Heart Failure Model for Testing Assist Devices
5 RO1 HL 24503-02

Dr. C. Forbes Dewey
Dept Mechanical Eng
Mass Inst of Tech
Room 3-250
Cambridge, MA 02139
(617) 253-2235
Unsteady Flow in Arterial Bifurcations
5 RO1 HL 21859-03

Dr. William H. Dobelle
Dept of Surgery
Columbia University
630 West 168th St
New York, NY 10032
(212) 694-4198
Simple Cardiac Assist (TALVB) Devices in Man
5 RO1 HL 23941-02

Dr. Leonard A.R. Gelding
Dept Cardiothor Surg
Cleveland Clinic
4500 Euclid Ave
Cleveland, OH 44106
(216) 444-6915
Physiological Studies of Chronic Nonpulsatile Blood Flow
1 RO1 HL 26267-01

Dr. Robert K. Jarvik
Inst Biomedical Eng
University of Utah
Bldg 518
Salt Lake City, UT 84112
(801) 581-6991
Studies with Electric Total Artificial Hearts
5 RO1 HL 24338-02

CIRCULATORY ASSIST & ARTIFICIAL HEART DEVICES PROGRAM

Dr. Adrian Kantrowitz
Dept of Surgery
Sinai Hosp of Detroit
6767 W Outer Dr
Detroit, MI 48235
(313) 272-6000 X8205
Active Prosthetic Myocardium: Effects on LV Function
5 RO1 HL 22329-02

Dr. Willem Kolff
Inst for Biomed Eng
University of Utah
Bldg 518
Salt Lake City, UT 84112
(801) 581-6296
Intra Aortic Balloon Pumping in Small Animals
5 RO1 HL 20803-04

Dr. Willem Kolff
Inst for Biomed Eng
University of Utah
Bldg 518
Salt Lake City, UT 84112
(801) 581-6991
Studies Towards An Acceptable Artificial Heart for Man
2 PO1 HL 13738-09

Dr. Bayliss C. McInnis
Cullen College of Eng
University of Houston
4800 Calhoun
Houston, TX 77004
(713) 749-1574
Automatic Controls for the Artificial Heart
1 RO1 HL 25029-OIA1

Dr. J. D. Mortensen
Utah Biomed Test Lab
520 Wakara Way
Salt Lake City, UT 84108
(801) 581-6190
Chronic Total Cardiopulmonary Mechanical Substitution
5 RO1 HL 22661-02

Dr. Yukihiko Nose
Dept Artificial Orgns
Cleveland Clin Found
9500 Euclid Ave
Cleveland, OH 44106
(216) 444-2470
Biventricular Assist and Replacement Studies
5 RO1 HL 24286-02

Dr. Don B. Olsen
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(801) 581-6991
Artificial Heart Implant, Later Cardiac Transplant
1 RO1 HL 24419-02

Dr. Don B. Olsen
Div Artificial Orgns
University of Utah
Salt Lake City, UT 84112
(801) 581-6991
Studies of the Pneumatic Artificial Heart in Calves
1 RO1 HL 24561-01

Dr. Peer M. Portner
Andros, Inc.
2332 Fourth Street
Berkley, CA 94710
(415) 849-1377
NO1-HV-7-2938
Development of a Left Heart Assist Blood Pump
Expired: 9/14/80

Dr. David Lederman
Avco Everett Res Lab
2385 Revere Bch Pkw
Everett, MA 02149
(617) 389-3000
NO1-HV-7-2937
Left Heart Assist Blood Pumps
Expired: 9/14/80

Dr. Yukihiko Nose
Cleveland Clinic Fndn
9500 Euclid Ave
Cleveland, OH 44106
(216) 444-2470
NO1-HV-4-2960
Development & Evaluation of Cardiac Prostheses
Expired: 9/29/80

Dr. John C. Norman
Texas Heart Inst
6720 Bestner St
Houston, TX 77030
(713) 521-3121
NO1-HV-7-2936
Left Heart Assist Device Development
Expired: 9/29/80

Mr. Robert L. Whalen
Thermo Electron Corp
101 First Ave
Waltham, MA 02154
(617) 890-8700
NO1-HV-7-2934
Development of a Left Heart Assist Blood Pump
FY 80: -O-

Dr. Philip Litwak
Thoratec Labs Corp
2023 8th Street
Emeryville, CA 94710
(415) 658-7787
NO1-HV-7-2939
Develop and Evaluate Left Heart Assist Blood Pumps
FY 80: -O-

FABRICATION - Dr. Altieri

Mr. Victor Poirier
Thermo Electron Corp.
101 First Ave.
Waltham, MA 02154
(617) 890-8700
NO1-HV-9-2907
Fabrication of Cardiovascular Devices
FY 80: $292,156

Mr. Keith S. Buck
Thoratec Labs Corp.
4204 Hollis St.
Emeryville, CA 94608
(415) 658-7787
NO1-HV-9-2906.
Fabrication of Cardiovascular Devices
FY 80: $207,821

CLINICAL EVALUATION: LEFT VENTRICULAR ASSIST DEVICES - Dr. Watson

Dr. William F. Bernhard
Childrens Hospital
Medical Center
300 Longwood Ave
Boston, MA 02115
(617) 734-6000 X3261
NO1-HV-5-3007
Clinical Evaluation: Model X LVAD
FY 80: $23,068
Expired: 6/30/80

Dr. John C. Norman
Texas Heart Inst
6720 Bestner Street
Houston, TX 72025
(713) 521-3121
NO1-HV-5-3006
Clinical Evaluation: Model VII LVAD
FY 80: $32,053
Expired: 6/30/80

Mr. John M. Keiser
Thermo Electron Corp
101 First Ave
Waltham, MA 02154
(617) 890-8700 X409
NO1-HV-5-3008
LVAD: Clinical Evaluation of Temporary Assist
FY 80: $31,809
Expired: 6/30/80

IMPLANTABLE LEFT HEART ASSIST SYSTEMS - Dr. Altieri, Dr. Watson

Dr. John Moise
Dr. Yukihiko Nose
Aerojet General Corp
POB 1322.2 Dept 2150
Sacramento, CA 95813
(919) 355-2018
NO1-HV-O-2911
Implantable Electrohydraulic Left Heart Assist Device
FY 80: $1,076,181

Dr. Peer Portner
Andros, Inc.
2332 Fourth St
Berkeley, CA 94710
(415) 849-1377
NO1-HV-O-2908
Implantable Left Heart Assist Syatem
FY 80: $1,044,718

Dr. Param ISingh
Dr. David Lederman
Avco Everett Res Lab
2385 Revere Bch Pkw
Everett, MA 02149
(617) 389-300
NO1-HV-O-2913
Implantable Left Heart Assist Device
FY 80: $1,038,454

Dr. John C. Norman
Mr. Jack Chambers
Texas Heart Institute
6720 Bestner St
Houston, TX 77030
(713) 521-3121
NO1-HV-O-2915
Implantable Left Heart Assist Device
FY 80: $893,361

Mr. David B. Oernes
Dr. William F. Bernhard
Thermo Electron Corp.
101 First Ave
Waltham, MA 02154
(617) 890-8700
NO1 NV-O-2914
Implantable Left Heart Assist Device
FY 80: $1,083,466

PHYSICAL TESTING - **Dr. Watson**

Dr. Carl R. McMillin
Monsanto Res Corp
1515 Nicholas Rd
Dayton, OH 45407
(513) 268-3411 x211
NO1-HV-7-2918
Physical Testing of Circulatory Assist Device Polymers
Expired: 8/31/80

Dr. Robert W. Penn
Natl Bureau of Stnds
Materials Res Inst
Gaithersburg, MD 20760
(301) 921-2116
YO1-HV-8-0003
Physical Testing of Circulatory Assist Device Polymers
Expired:9/30/80

Dr. John L. Kardos
Washington University
Linden & Skinker
St. Louis, MO 63130
(314) 863-0100 x4577
NO1-HV-7-2919
Physical Testing of Circulatory Assist Device Polymers
Expired: 8/31/80

PHYSICAL TESTING - Dr. Altieri

Dr. Carl R. McMillan
Monsanto Res Corp
1515 Nicholas Rd
Dayton, OH 45407
(513) 268-3411 x211
NO1-RV-O-2909
Physical Testing of Circulatory Assiat Device Polymers
PY 80: $208,762

Dr. John L. Kardoa
Washington University
Linden & Skinker
St Louis, MO 63130
(314) 889-6062
NO1-HV-O-291O
Physical Testing of Circulatory Assist Device Polymers
PY 80: $145,992

ENERGY TRANSMISSION - Dr. Berson

Dr. Peer M. Portner
Andros, Inc
2332 Fourth Street
Berkeley, CA 94710
(415) 849-1377
NO1-NV-7-2933
Electrical Energy Transmission Technique Development
FY 80: $219,323

Dr. Adrian Kantrowitz
Sinai Hosp of Detroit
6767 West Outer Dr
Detroit, MI 48235
(313) 493-5775
NO1-NV-8-2921
Percutaneous Energy Transmission Systems
FY 80: $116,263

Dr. Benedict D.T. Daly
St Elizabeth's Hosp
736 Cambridge St
Boston, MA 02135
(617) 956-5589
NO1-HV-8-2919
Percutaneous Energy Transmission Systems
FY 80: $141,092

Dr. Freeman Fraim
Thermo Electron Corp
101 First Ave
Waltham, MA 02154
(617) 890-8700
NO1-HV-O-2903
Develop, Evaluate Transcutaneous Energy Transmission System
FY 80: $202,507

INSTRUMENTATION - **Dr. Berson**

Dr. Ralph W. Barnes
Bowman Gray
School of Medicine
300 Hawthorne Rd
Winston-Salem, N.C.27103
(919] 727-4504
NO1-HV-1-2902
Noninvasive Detection of Atherosclerotic Lesions
FY 81: $296,830

Dr. Charles A. Histretta
Univ of Wisconsin
Clinical Science Ctr
600 Highland Ave
Madison, WI 53706
(608) 263-8309
NO1-HV 1-2905
Noninvasive Detection of Atherosclerotic Lesions
FY 81: $296,830

Dr. John D. Hestenes
Calif Inst of Tech
Jet Propulsion Lab
4800 Oak Grove Dr
Pasadena, CA 91103
(213) 354-2961
Imaging of Deep Arterial Lesions by Swept Ultrasound

Dr. William R. Brody
Stanford University
Dept of Radiology
Stanford, CA 94305
(415) 497-5226
NO1-HV-O-2922
Energy Selective Methods for Intravenous Arteriography
FY 80: $246,359

Dr. Donald Sashin
Univ of Pittsburgh
RC 406 Scafe Hall
Pittsburgh, PA 15621
(412) 647-3490
NO1-HV-O-2929
Noninvasive Detection of **Atherosclerotic Lesions**
FY 80: $181,251

INSTRUMENTATION - Mr. Powell

Dr. Ralph W. Barnes
Bowman Gray
School of Medicine
300 S Hawthorne Rd
Winston Salem, N.C.27103
(919) 727-4504
NO1-HV-7-2925
Ultrasonic Imaging and Arterial Measurements
Expired: 9/14/80

Dr. Frank E. Barber
Harvard Med School
44 Bimey St
Boston, MA 02115
(617) 732-3582
NO1-HV-7-2927
Ultrasonic Imaging and Tisaue Characterization
Expired: 9/29/80

Dr. John M. Reid
Institute of Applied
Physiology & Medicine
701-16th Ave
Seattle, WA 98122
(206) 442-7330
NO1-HV-7-2926
Ultrasonic Doppler I-ging with Automatic Line Scanning
Expired: 9/14/80

Dr. Titus C. Evans
Mayo Foundation
200 First Ave.
Rochester, MN 55901
(507) 282-2511
NO1-HV-7-2928
Ultrasonic Imaging with Flow Velocity Profiles
Expired: 9/17/80

Dr. David Wilson
SRI International
Bioengineering Res
333 Ravenswood*Ave
Menlo Park, CA 94025
(415) 326-6200 X4918
NO1-HV-2900
Duplex B-Scan Imaging System for Abdominal Arteries
FY 81: $346,130

Dr. Leon Kaufmann
Univ of Calif at SF
400 Grandview Dr
San Francisco, CA94080
(415) 952-1366
NO1-HV-O-2928
Noninvasive Detection of Atherosclerotic Lesions
N 80: $87,361

Dr. Charles P. Olinger
Univ of Cincinnati
Stroke Research Lab
4303 ?led Sci Bldg
Cincinnati, OH 45267
(513) 872-5431
NO1-HV-7-2924
Ultrasonic Imaging with Flow & Tissue Characterization
FY 80: $266,478
Expired: 9/1/80

Dr. Martin D. Fox
Univ of Connecticut
School of Eng
Storrs, CT 06268
(203) 486-4821
NO1-HV-7-2929
Crossed Beam Doppler and Sector Scans
Expired: 9/1/80

INSTRUMENTATION - Mr. Powell

Dr. David H. Blankenhorn
Univ of So. Cal.
2025 Zonal Ave
Los Angeles, CA 90033
(213) 224-7315
NO1-NV-7-2930
Enhanced X-ray Images and Ultrasonic Tissue Parameters
Expired: 9/29/80

Dr. Theron W. Ovitt
University of Arizona
Dept of Radiology
Tucson, AZ 85724
(602) 626-6007
NO1-HV-7-2931
Electronic X-ray Imaging & New Contrast Agents
Expired: 9/1/80

Dr. Theron W. Ovitt
Univ of Arizona
Dept of Radiology
Health Sciences Ctr
Tuscon, AZ 85724
(602) 626-6007
NO1-NV-1-2901
Noninvasive Detection of Atherosclerotic Lesions
FY 81: $257,159

Dr. Peter Madras
Dr. Robert C.Cumming
Avco Everett Res Lab
2385 Revere Bch Pkw
Everett,MA 02149
(617)389-3000
NO1-HV-O-2912
Blood Compatibility of Circulatory Assist Devices
FY 80: $142,885

Dr. G. C. Berry
Carnegie-Mellon Inst.
4400 Fifth Avenue
Pittsburgh, PA 15213
(412) 578-3131
NO1-HV-3-2949
Interpenetrating Polymer Networks for Biological Application:
Expired: 3/31/80

Dr. Edward W.C. Wong
Avco Everett Res Lab
2385 Revere Bch Pkw
Everett,MA 02149
(617) 389-3000 X765
NO1-HV-9-2932
Procurement of Standard Reference Materials
FY 80: $81,968

Dr. Paul Didisheim
Mayo Foundation
200 First St. , SW
Rochester, MN 55901
(507) 284-3049
NO1-HV-9-2915
Blood Compatibility of Circulatory Assist Devices
FY 80: $137,687

Dr. George Herzlinger
Avco Everett Res. Lab
2385 Revere Bch Pkw
Everett,MA 02149
(617) 389-3000 X305
NO1-HV-9-2901
Complement-Biomaterial Interaction
Expired: 3/31/80

Mr. Robert S. Ward
Thoratec Labs Corp.
2023 Eighth Street
Berkeley, CA 94710
(415) 658-7787
NO1-HV-9-2933
Procurement of Standard Reference Materials
FY 80: $237,248

Mr. Axel D. Haubold
Carbomedics
11388 Sorrento Vail
‘San Diego, CA 92111
(714) 452-8484
NO1-HV-4-2928
Carbon Film Composites for Prosthetic Devices
Expired: 4/30/80

f310MATERIALS - Mr. Powell

Mr. Michael Szycher
Thermo Electron Corp.
101 First Ave
Waltham, MA 02154
(617) 890-8700
N01-HV-32915
Development & Testing of **Integrally Textured Blood Pump Bladders**
FY 80: -O-

Dr. William W. Lee
Stanford Res Inst
333 Ravenswood Ave
Menlo Park, CA 94025
(413) 326-6200
Blood Compatible Benzamidine Containing Polymers
5 RO1 HL 21769-03

Dr. Robert I.Leininger
Battelle Mem Inst
Columbus Laboratories
505 King Avenue
Columbus,OH 43201
(614) 424-7138
An Evaluation of Blood-Surface Interactions
5 RO1 HL 24015-02

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Childrns Hosp Med Ctr
300 Longwood Ave
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(617) 734-6000 X3619
Blood-Material Interactions
5 RO1 HL 24029-02

Dr. Reginald G. Mason
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Endothelial Linings for Artificial Organs
7 RO1 HL 25805-01

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An Inhibitor of Platelet Adhesion to Artificial Organs
7 RO1 HL 25806-01

Dr. Larry V. McIntire
Dept of Chem Eng
Rice University
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(713) 528-4141 X41O
Perfusion Lung: Role of Traumatized Leukocytes
5 RO1 HL 17437-05

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Platelet Factor 3 and Blood-Material Interactions
1 RO1 HL 25804-01

Dr. John A. Penner
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College of Human Med
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(517) 353-6625
Control of Clotting on Biomaterials by Anticoagulants
7 RO1 HL 27042-01

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Center for Hlth Sci
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Surface-Active Antithrombotic Agents for Prostheses
5 RO1 HL 22236-02

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Moieties Affecting Platelet - Biomaterial Interactions
1 RO1 HLGM 25884-01

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Blood-Material Interactions
5 RO1 HL 24018-02

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Thromboresistant Materials
5 RO1 HL 20079-04

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Effect of Flow on Fibrin Formation
1 RO1 HL 23379-01

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Blood Material Interface Interactions
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5 PO1 HL 15195-04

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(415) 642-4525
Hemolysis Induced by Shear Flow
5 RO1 HL 23274-02

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3837 Simpsn-Strt Rd
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Development of Antithrombogenic Plastic Biomaterials
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Thrombogenic/Non-thrombogenic Collagen Fibers
5 RO1 HL 24036-02

APPENDIX D: SHDPP MATERIALS

Table D-1.—SHDPP Three= Community Study Design

CommuniTY	1972	1973	1974	1975
Watsonville. .	Baseline survey	Media campaign intensive instruc- t ion for 2/3	Second survey Media campaign intensive instruc- tion for 2/3	Third survey Maintenance (low level) media campaign
Gilroy	Baseline survey	Media campaign	Second survey Media campaign	Third survey Maintenance (low level) media campaign
Tracy.	Baseline survey		Second survey	Third survey

SOURCE: Stanford Heart Disease Prevention Program, Stanford, Calif.

Table D-2.—Demographic Characteristics and Survey Response Rates in Each of the Three Communities

Characteristics oft he community groups	Tracy	Gilroy	Watsonville
Entire town (1970 census)			
Population (total)	14,724	12,665	14,569
Population (35 to 59 years of age)	4,283	3,224	4,115
Mean age of 35-to 59-year-old group (years)	47.0	46.2	47.6
Male/female ratio of 35-to 59-year-old group	0.96	0.88	0.86
Random sample (ages 35 to 59)			
Original sample	659	6 9	833
Natural attrition (migration or death)	74	79	107
Potential participants for all 3 surveys	585	580	726
Percentage of original sample	88.8%	88.0%	87.1%
Refusals and dropouts over 2 years	201	183	303
Participants completing first and third survey	418	427	449
Percentage of potential participants	72%	74%	62%
Mean age at October 1972 (years)	46.9	45.8	48.4
Male/female ratio	0.84	0.78	0.75
Spanish speaking	3.170	8.370	7.8%
Bilingual	6.0%	17.970	9.5%
High school completed	68.5%	63.5%	64.7%
Annual family income of $10,000	68.9%	65.3%	62.2%

SOURCE: Stanford Heart Disease Prevention Program, Stanford, Cal if.

Table D-3.—Risk Indicator and Knowledge Scores: Percentage Change From Baseline at 1,2, and 3 Followup Surveys

	Treatment			
Measurement	Watsonville: media plus face-to-face (N= 67)	Watsonville: media only (N= 37)	Gilroy: media only (N= 85)	Tracy: control (N= 90)
Risk score				
Followup 1	– 27.8a	– 11.6[b]	— 81b	5.7
Followup 2	– 30.1 b	–25.6b	– 25.5b	– 2.3
Followup 3	–29.OC	– 23.1 [b]	– 16.1	– 8.0
Knowledge score				
Followup 1	51 .6a	27.4[b]	16.6[b]	2.2
Followup 2	53.3a	27.7[b]	28.0[b]	4.8
Followup 3	57.0[a]	27.9[b]	33.9[b]	14.0
Dietary cholesterol (mg/day)				
Followup 1	–40.7d	– 26.1 b	–29.8b	–10.1
Followup 2	- 37.l[b]	–22.9b	–31.8b	– 6.5
Followup 3	–42.3b	–27.2b	–38.6b	– 13.4
Dietary saturated fat (g/day)				
Followup 1	–33.4b	–20.9b	–25.8b	–11.1
Followup 2	–30.5b	– 17.0	– 30.1 b	– 5.1
Followup 3	–36.4b	–23.9b	–38.4b	– 7.0
Relative weight				
Followup 1	— 3.6a	0.0	- 0.3	- 0.7
Followup 2	– 1.5	0.0	- 0.2	- 0.4
Followup 3	– 0.4	– 0.8	0.4	- 0.8
Cigarette smokers (%)				
Followup 1	–32.5d	0.0	– 15.1	– 6.4
Followup 2	- 47.5a	O . O[b, c]	– 15.1	– 10.6
Followup 3	–50.oa	O . O[b, c]	– 11.3	– 14.9

NOTE: The treatment groups consist of individuals who attended baseline and all three annual followup surveys. Data are reproduced from Meyer, et al.
[a]The between.group, one-tailed t-test with each other group iS Significant: P ˙005
The between-group, one-tailed t-test with Tracy is significant: p <0.05.
[c]The betweefl-group, one-tailed t-test with Tracy and Gilroy is significant: P <005
[d]The between-group, one.tailed t test with Watsonville Control and Tracy iS signifiLa,lt: P <0.05.
[e]Between-group difference is in the direction contrary to prediction.

SOURCE: Stanford Heart Disease Prevention Program, Stanford, Calif.

Table D-4.—SHDPP Expenses by Media Campaign

	Campaign 1	Campaign 2	Campaign 3	Total
Media costs	$120,150	$74,246	$33,930	$228,326
Personnel	87,960	57,958	69,153	215,071
Surveys and data	33,243	20,639	18,198	72,080
Total	$241,353	$152,843	$121,281	$515,477
Number of months				
Average/month	$8,045	$12,737	$10,107	$9,545

SOURCE. Stanford Heart Disease Prevention Program, Stanford, Cal if

REFERENCES

1. Ad Hoc Task Force on Cardiac Replacement, ***Cardiac Replacement: Medical, Ethical, Psychological, and Economic Implications*** (Washington, D. C.: U.S. Government Printing Office, 1969).
2. American Heart Association, "Intersociety Commission for Heart Disease Resources, " ***Circulation,*** 42:A55, 1970.
3. American Hospital Association, ***Hospital Statistics*** (Chicago: AHA, published annually).
4. Anderton, J. L., et al., ***Living With Renal Failure*** (Baltimore, Md.: University Park Press, 1978).
5. Annas, G., "Rationing Health Technology: Legal and Ethical Issues, " in ***Technology and the Quality of Health Care,*** R. H. Egdahl and P. M. Gertman (eds.) (Germantown, Md.: Aspen Systems Corp., 1978).
6. Arthur D. Little, Inc., *Final* ***Report: An Evaluation of Home Hemodialysis Systems (2*** vols.), final report to Kidney Disease Control Program, Health Services and Mental Administration, Public Health Service, DHEW, Rockville, Md., 1970.
7. Arthur D. Little, Inc., ***Financing Catastrophically Expensive Health Care (2*** vols.), contract No. HSM 11o-71-197, final report to Health Resources Administration, Public Health Service, DHEW, Rockville, Md., 1975.
8. Banta, H. D., and Sanes, J. R., "How the CAT Got Out of the Bag," in ***Technology and the Quality of Health Care,*** R. H. Egdahl and P. M. Gertman (eds.) (Germantown, Md.: Aspen Systems Corp., 1978).
9. Barnes, B. A., Harvard School of Public Health, "Current Status of Home Dialysis and Related Issues Based Upon Literature of 1977-1979, " unpublished manuscript, 1979.
10. _____, "An Overview of the Treatment of End-Stage Renal Disease and a Consideration of Some of the Consequences," in Costs, ***Risks, and Benefits of Surgery,*** J. P. Bunker, et al. (eds.) (New York: Oxford University Press, 1977).
11. Befeler, B., "Cost Analysis of Elective Myocardial Revascularization," ***Chest,*** 72(4):548, 1977.
12. Bilitch, M., "Performance of Cardiac Pacemaker Generators," ***PACE,*** 2:259, ***1979.***
13. Calabresi, G., and Bobbitt, P., ***Tragic Choices (New*** York: W. W. Norton & Co., 1978).
14. California State Department of Public Health, ***The Feasibility of Chronic Hemodialysis in California*** (Berkeley, Calif.: State of California, 1966).
15. Calland, C., "Iatrogenic Problems in End-Stage Renal Failure," *N. Eng. J. Med.* 287:334, ***1972.***
16. Cardiology Advisory Committee, "Mechanically Assisted Circulation" (Bethesda, Md.: National Heart, Lung, and Blood Institute, May 1977).
17. Chardack, W., et al., "Correction of Complete Heart-Block by Self-Contained Pacemaker," *J. Thor. Cardio. Surg.* 42:814, ***1961.***
18. Chiang, C. L., ***Introduction to Stochastic Processes in Biostatistics (New*** York: John Wiley & Sons, 1968).
19. Christopherson, L. K., et al., "Rehabilitation After Cardiac Transplantation, " *J. A.M.A.* 236(18): 2082, 1976.
20. Cole, D., Human Health and Assessments, Office of Health and Environmental Research, Department of Energy, Washington, D. C., personal communication, July 1979.
21. Comroe, J. H., University of California, San Francisco, interview, Sept. 21, 1979.
22. Cooper, T., Cornell University, Ithaca, N. Y., personal communication, May 25, 1979.
23. Copley, D. P., et al., "Improved Outcome for Prehospital Cardiopulmonary Collapse With Resuscitation by Bystanders, " ***Circulation*** 56:901, ***1977.***
24. Crosby, I. K., et al., "Employment and Survival After Left Main Coronary Surgery," *Circulation* 58:18, ***1978.***
25. Czaczkes, J. W., and De-Nour, A. K., ***Chronic Dialysis as a Way of*** Life (New York: Brunner/Mazel, 1978).
26. Dong, E., and Andreopoulos, S., ***Heartbeat (New*** York: Coward, McGann & Geoghegan, 1978).
27. Farquhar, J. W., et al., "Community Education for Cardiovascular Health," *Lancet* 1:1192, ***1977.***
28. Fox, R. C., and Swazey, J. P., ***The Courage to Fail*** (Chicago: University of Chicago Press, 1974).
29. Friedberg, C. K., et al., "Non-Surgically Acquired Heart Blocks," ***Ann. IV. Y. Acad. Sci.*** 11:835, ***1964.***
30. Frommer, P., National Heart, Lung, and Blood Institute, Bethesda, Md., personal communication, March 1980.
31. Furman, S., and Escher, D., ***Principles and Techniques*** of ***Cardiac Pacemaking (New*** York: Harper & Row, 1979).
32. Hammermeister, K. E., et al., "The Effect of Surgical Versus Medical Therapy of Coronary Disease on Return to Work, " ***Amer. J. Card. 41:409, 1978.***

33. Hastings, F., in hearings on HEW Appropriations for 1968, Senate Subcommittee on Appropriations, 90th Cong., 1st sess. (Washington, D. C.: U.S. Government Printing Office, 1967).
34. Hegyeli, R., and Machesko, M., *Report on the Left Ventricular Assist Device: Teco Models VII and X,* DHEW publication No. (NIH) 75-626 (Bethesda, Md.: National Institutes of Health, January 1974).
35. Hittman Associates, ***Final Summary Report on Six Studies Basic to the Consideration of the Artificial Heart Program*** (Baltimore, Md.: Hittman Associates, 1966).
36. Johansson, B., "Longevity in Complete Heart Block," Arm. *N.Y. Acad. Sci.* 167:1031, *1969.*
37. Kantrowitz, A., et al., "The Treatment of Complete Heart Block With an Implanted Pacemaker," *Surg.* Gyn. Ob. 115:415, 1962.
38. Kaplan, A., "Artificial Heart Panel," ***Hastings Center Report*** 5:41,1975.
39. Katz, J., and Capron, A. M., ***Catastrophic Diseases: Who Decides What? (New*** York: Russell Sage Foundation, 1975).
40. Knutti, R., in hearings on HEW Appropriations for 1966, Senate Subcommittee on Appropriations, 89th Cong., 1st sess. (Washington, D. C.: U.S. Government Printing Office, 1965).
41. Kolff, W. J., and Lawson, J., "Perspectives for the Total Artificial Heart, " ***Transplantation Proceedings*** 9(1):317, March 1979.
42. Lederberg, J., "The Heart Gap Will Cause Soul Ache," Washington ***Post,*** Washington, D. C., July 24, 1966.
43. Levy, N. B. (cd.), ***Living or Dying*** (Springfield, Ill.: Charles C. Thomas, 1974).
44. Liberthson, R. R., et al., "Pre-Hospital Ventricular Defibrillation: Prognosis Follow-Up Course," *N.Eng.J.* Med. 91:317, 1974.
45. Lindgren, N., "Artificial Heart—Examples of Mechanical Engineering Enterprise, " *IEEE Spectrum,* September 1967.
46. McAnulty, J. H., et al., "A Prospective Evaluation of Intrahislan Delay, " ***Circulation*** 59:1035, 1979.
47. McIntosh, H. D., and Garcia, J. A., "Aortocoronary Bypass Grafting 1967-1977, " *Circulation* 57(3):405, 1978.
48. Meyer, A., et al., Stanford Heart Disease Prevention Program, Stanford, Calif., "Skills Training in a Cardiovascular Health Education Campaign," unpublished manuscript.
49. National Academy of Sciences, Institute of Medicine, "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation" (Washington, D. C.: National Academy of Sciences, November 1972).
50. National Heart and Lung Institute, *Totally Implantable Nuclear Heart Assist and Artificial Heart Devices* (Bethesda, Md.: National Institutes of Health, February 1972).
51. National Institutes of Health, ***The Totally Implantable Artificial Heart: Economic,*** Ethical, *Legal, Medical, Psychiatric,* and *Social* Implications, NIH publication No. 74-191 (Bethesda, Md.: National Institutes of Health, 1973).
52. Norman, J., Texas Heart Institute, Houston, Tex., interview, January 1979.
53. _____, "Mechanical Cloning, " *J. Art. Int. Org.* 2:235, 1978.
54. Nosé, Y., Cleveland Clinic, Cleveland, Ohio, personal communication, 1979.
55. Parsonnet, V., "Appraisal and Reappraisal of Cardiac Therapy, " ***Am. Heart*** *J.* 94(5):658, 1977.
56. Parsonnet, V., and Manhardt, M., "Permanent Pacing of the Heart, 1952 to 1976, " ***Am. J. Card.*** 39:250, 1977.
57. Pierce, W., Pennsylvania State University, Hershey, Pa., personal communication, 1980.
58. Poirier, V., Thermoelectron Corp., Waltham, Mass., personal communication, July 1979.
59. Preston, T., ***Coronary Artery Surgery (New*** York: Raven Press, 1977).
60. Puska, P., et al., "Changes in Coronary Risk Factors During Comprehensive Five-Year Community Programme to Control Cardiovascular Diseases (North Karelia Project)," *Br.* Med. *J.* 2:1173, 1979.
61. Raizes, G., et al., "Instantaneous Nonarrhythmic Cardiac Death in Acute Myocardial Infarction, " ***Am. J. Card.*** 39(1):1, 1977.
62. Reiss, J. B., et al., Washington, D. C., "Issues in the Cost and Regulation of New Medical Technologies and Procedures: Heart Transplants as a Case Study," unpublished paper, 1980.
63. Rettig, R. A., "The Policy Debate on Patient Care Financing for Victims of End-Stage Renal Disease," ***Law*** *Contemp. Probl.* 40(4):196, 1976.
64. Rettig, R. A., and Webster, T. C., "Implementation of the End-Stage Renal Disease Program: A Mixed Pattern of Subsidizing and Regulating the Delivery of Medical Services, " in ***Toward A National Health Policy,*** K. Friedman and S. Radkoff (eds.) (Lexington, Mass.: Lexington Books, 1977).
65. Rimm, A., et al., "Changes in Occupation After Aortocoronary Bypass, " ***J. A.M.A.*** 236(4):361, 1976.
66. Russell, R. O., et al., "Changes in Work Status

for Surgical Versus Medical Therapy," *Am. J. Card.* 43:383, *1979.*
67. Salonen, J. T., et al., "Changes in Morbidity and Mortality During Comprehensive Community Programme To Control Cardiovascular Diseases During 1972-7 in North Karelia," *Br. Med. J.* 2:1178, *1979.*
68. Samet, P., *Cardiac Pacing (New* York: Grune & Stratton, 1973).
69. Sanders, H., "Artificial Organs," *Chem. & Eng. N.* 49:68, 1971.
70. Sapolsky, H. M., "Here Comes the Artificial Heart," *The Sciences* 13:26, 1978.
71. Schroeder, J., "Current Status of Cardiac Transplantation, 1978," *J, A.M.A.* 241(19):2069, *1979.*
72. Stanford Heart Disease Prevention Program, Stanford, Calif., personal communication, 1980.
73. Stinson, E. B., "Current Status of Cardiac Transplantation," in *Heart Failure,* A. P. Fishman (cd.) (Washington, D. C.: Hemisphere Publishing Co., 1978).
74. Stoney, W. S., et al., "Cost of Cardiac Pacing," *Am. J.* Card. 37:23, 1976.
75. Symmes, J. C., et al., "Influence of Aortocoronary Bypass Surgery on Employ merit," *CMA Journal* 118:268, *1978.*
76. Tsai, S. P., et al., "Effect of Reduction in Leading Causes of Death," *Am. J. Public Health* 68(10):966, *1978.*
77. Watson, J., National Heart, Lung, and Blood Institute, Bethesda, Md., interview, June 1979.
78. Zoll, P. M., et al., "Long-Term Electric Stimulation of the Heart," *Ann. Surg.* 154:330, *1961.*

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