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THE ARTIFICIAL HEART

Costs, Risks, and Benefits—An Update

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INTRODUCTION

For several decades, major advances in medicine have increased dramatically our ability to prevent, diagnose, and manage a wide variety of chronic and acute health problems. However, medical innovations also pose significant economic, social, and ethical questions. How do we best utilize scarce medical resources? How do we balance anticipated benefits against the dollar cost or associated risk? What is the impact on total health care spending now and in future years? As concern over these issues grows concomitant with increased health care spending, technology assessment is often promoted as a method for determining whether a biomedical innovation should be encouraged to disseminate rapidly in order to maximize its benefits to individual patients, or constrained to develop slowly in order to minimize collective costs or risks. But, the art and practice of evaluating medical technologies, especially innovations still in the research and development phase, are not well developed (6;8;11;14;16;34;35).

The recent and well publicized implantations of the Jarvik-7 artificial heart under a Food and Drug Administration (FDA) investigational device exemption presents an opportunity and a challenge for technology assessment (12;22;36). Federal research funding for the development of an artificial heart commenced in the mid-1960s and has amounted to approximately $200 million or $10 million per year (21). The realization of an artificial heart which does not produce clotting or hemolysis, that delivers appropriate blood flow, and that has a totally implantable or portable power source, is still many years away (19); when the artificial heart is perfected, it will have a substantial impact on those who suffer from cardiac disease, increasing their life expectancy without the immunological and availability problems of donor organs. It will also be very costly, beyond the reach of most Americans, unless it is reimbursed by third party insurors. These significant costs (an estimated quarter of a million dollars per patient) may limit the use of the technology, even though the device may be the only viable therapy for

a specified and significantly large group of patients. It may also be true that the costs of implantation and continuing medical care for artificial heart patients are justified and appropriate when considered in light of other currently accepted, costly therapies, such as neonatal intensive care, plasmapheresis (the exchange of blood plasma), or the transplantation of other internal organs. Currently, there is not sufficient information available to make an assessment of the artificial heart's cost and efficacy; however, as investigational procedures continue, a growing body of data will become available for analysis.

In 1981, the author completed a study of the cost-effectiveness of the artificial heart for the Congressional Office of Technology Assessment (OTA) (21). At that time, I was constrained by the lack of any data on human implantations, although there was a body of literature on animal trials. Instead, I relied on the clinical experience and costs of related health care technologies, such as heart transplants, coronary bypass surgery, the cardiac pacemaker, and kidney dialysis. In this paper I wish to draw on that experience to discuss the parameters critical for any assessment of the cost-effectiveness of the artificial heart, and the extent to which changes in these parameters will impact short term and long term expenditures for the device.

MEDICAL TECHNOLOGY ASSESSMENT

Concern over the artificial heart is a concrete representation of the larger debate over whether society should consider both the medical (efficacy and safety) and social (economic, ethical, legal) consequences before widespread dissemination and third party reimbursement for biomedical innovations is encouraged (1;7). These issues are predominant today because of the contribution that health care technology makes to rising health expenditures. Medical technology is estimated to account for anywhere from 25% to 75% of increased health expenditures (2;9;25;31). Costs result from the introduction of costly and dramatic technologies, like the artificial heart and computerized axial tomography (CAT) scanners; from the widespread use of therapeutic procedures, such as kidney dialysis and coronary artery bypass graft; as well as from the high volume use of less expensive diagnostic tests, such as blood chemistries.

It is not easy, however, to control the dissemination of medical innovations once they have been developed. Doctors want to provide the best care for their patients and are hesitant to ration treatment even though it is costly. In the early days of hemodialysis, when resources were insufficient to meet the need, there was concern that 25% to 50% of the patients who needed dialysis were not able to obtain it. Institutional screening committees were appointed in certain localities to decide who would receive the therapy. This painful selection process was abated when the U.S. Congress enacted legislation in 1972 extending Medicare coverage to the treatment of end-stage renal disease (ESRD) (20;29). The decision to cover hemodialysis under Medicare stimulated increased diffusion and utilization of the therapy and resulted in continuing high costs (15;29). Implicit or explicit rationing of health care services will become more evident as additional high cost innovations, such as the artificial heart or liver transplants, become recognized therapy and health care funds are insufficient to cover the procedures for all potential patients (1).

Today, public policy is increasingly likely to determine to what extent emerging therapeutic procedures or diagnostic tests will be reimbursed by both public and private insurers (16;32;34). These coverage decisions, in turn, will influence the rate of diffusion. There have been some steps taken to encourage systematic analyses of health care technology, although they have not always been successful. The National Center for Health Care Technology (NCHCT) was established in 1978 to evaluate biomedical innovations, but the NCHCT was phased out due to lack of funding. In 1984, the U.S. Congress broadened the responsibilities of the National Center for Health Services Research (PL 98-551) to include research on health care technology. The Congressional Office of Technology Assessment has provided significant support for the evaluation of medical innovations for a number of years (34).

Technology assessment involves the coordination of existing research, clinical information, and informed judgment regarding the safety, efficacy, and cost-effectiveness of a strategy for dealing with a specific health problem or the delivery of health services. While the extent to which a technology performs reliably and safely has been the traditional focus of health technology assessment, current work has broadened substantially the scope to include non-medical criteria, such as short and long term social, economic, ethical, and legal impacts (34). The basis of much of this evaluation is cost-effectiveness analysis. The purpose is to measure the value of an investment in a health innovation, i.e., comparing costs with beneficial changes in health (35). While the concept sounds straightforward—comparing costs with the resulting effectiveness—applications can be very complex, because there is no definitive link between how changes in health technology affect costs or vice versa. In most cases, the effects are conditional on the user, the health of the patient, and the extent to which a technological product or a procedure performs reliably and safely.

Extrapolating estimates of costs and effectiveness of any emerging technology from small-scale clinical trials includes consideration of the following parameters:

1. the need for the innovation as determined by the number of potential recipients of a procedure or users of a medical device;
2. the legal and ethical concerns related to the availability of the technology;
3. the availability of or constraints on the health resources required by the technology, such as trained personnel, facilities with suitable equipment, or certain biomaterials;
4. estimates of the medical costs, such as in-patient and out-patient charges, professional fees, drugs, and medical devices, that are directly related to the technology at the time of initial use and continuing throughout the patient's lifetime;
5. estimates of the effectiveness of the innovation measured in terms of increased life expectancy, lives saved, quality of life, or similar indicators of mortality or morbidity; and
6. alternative therapies (medical and surgical) directed at the same patient population.

In the following sections, I discuss these parameters as related to the artificial heart and make estimates based on currently available data. With an awareness that the technology will be changing, and that costs and death rates from cardiac

disease are also changing independent of medical care, I will develop a range of estimates.

POTENTIAL RECIPIENTS

The permanent artificial heart is designed to replace the function of the natural heart in patients who cannot otherwise maintain normal circulation with any form of circulatory support. In addition, the artificial heart may be used as an interim support device (a "bridge") for patients awaiting cardiac transplantation. However, that group of patients will not be considered in this discussion. Three major groups of patients have been identified as potential candidates for the artificial heart (5;12;13;21;36):

1. persons undergoing open heart surgery in whom the heart is unable to reassume the hemodynamic load from the cardiopulmonary bypass pump after surgery;
2. persons with worsening end-stage heart failure resulting from idiopathic cardiomyopathy, ischemic heart disease, or similar causes; and
3. survivors of a myocardial infarction and/or cardiac arrest with worsening course and inoperable disease.

Candidates in the first group would be primarily patients who are unable to be weaned from the pump after open heart surgery for coronary artery bypass graft, cardiac valve replacement, and muscle resection. The second group would include persons with ischemic heart disease (HD); patients with severe cardiomyopathy 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. In order to be candidates, members of the third group would have to survive an attack or cardiac arrest through transportation to the hospital, treatment in the emergency room, and initial stabilization. In addition, all three groups of patients must be able to survive for a minimum of one hour after the replacement decision is made to prepare for the implantation.

Potential candidates for biventricular assistance are also assumed to be ineligible for any other form of circulatory support, such as cardiac transplantation or temporary and permanent left ventricular assistance. Currently, persons over 55 years of age do not qualify for cardiac transplantation. In addition, the initial protocol for the implantation of the Jarvik-7 artificial heart, which was approved by the FDA in 1982, determined that implant recipients must be free of other life-threatening systemic illnesses (e.g., cerebrovascular disease, atherosclerosis, or chronic renal failure), and have no evidence of systemic infection. The method for determining the number of patients in each of the three groups who would be eligible each year for total mechanical circulatory support is detailed in Appendix 1. Approximately 2,000 persons each year cannot be weaned from the cardiopulmonary bypass pump. The second group includes approximately 10,000 persons with severe end-stage cardiac disease. The third group includes approximately 116,500 persons of all ages who suffer acute cardiogenic shock. I estimate a total of 32,500 potential candidates annually after the application of age and medical criteria.

If the prevailing medical or age screens are relaxed over time to accommodate sicker or older patients, this figure might increase substantially. Conversely, if many potential candidates choose not to accept treatment with this device, the number of candidates might be substantially lower. To allow for this possibility, I have also calculated lower bound (11,500 persons) and upper bound (64,000 persons) estimates, as indicated in Appendix 1.

The current group of devices available for implantation (such as the Jarvik-7) further limit the patient pool to very large females and males over 145 pounds. Some patients weighing less may be candidates if their chest cavities can accommodate the heart, which is slightly larger than the normal human heart. This limitation was not taken into account in our determination of the potential recipients, because investigational work has commenced on the smaller Jarvik-70 artificial heart which will be available for use in women and small men.

LEGAL AND ETHICAL CONSIDERATIONS

As mentioned in the previous section, there are three groups of patients who would be potential recipients for the artificial heart. However, the initial investigational protocol developed for the implantation of the Jarvik-7 required that the prospective patient provide informed consent twice, with a minimum 24-hour waiting period after the first signature. The approved protocol emphasized that the need for the patient's conscious understanding of the procedure, the current state of knowledge regarding artificial heart implantation, quality of life, and treatment alternatives were essential to truly informed patient consent. These criteria supplement earlier medical and psychological evaluation of the patient by the hospital selection committee (36).

The required mandatory waiting period for signature of the consent form, and the fact that the consent form must be signed by the patient, effectively eliminates the third and largest group of patients—those persons who have suffered an acute coronary event. Patients in the first group who are scheduled to undergo open heart surgery must sign the consent form prior to entering surgery. Consequently, only two categories of patients are, in reality, eligible for the artificial heart.

The continued application of this protocol would limit the pool of potential recipients to approximately 12,000 persons per year. In order for the pool to expand to include patients who suffer acute cardiogenic shock, the protocol would need to be changed to allow informed consent by the patient's family, without the mandatory 24-hour waiting period. Truly informed consent would be difficult to obtain under these circumstances.

The critical issue in expansion of the protocol to include the third group is the ability to determine when death is imminent in a person suffering an acute cardiac event. The University of Utah Institutional Review Board (36) expressed such concerns when they designed the initial protocol. Similar ethical concerns were discussed by the Artificial Heart Working Group in their 1982 report (5). However, if the device does prove to be successful and the informed consent protocol is relaxed, then the procedure may be extended to this larger group of eligible candidates, bringing the total to predicted levels of approximately 32,500 patients annually.

AVAILABILITY OF RESOURCES

An important consideration in planning for the clinical application of the artificial heart is the adequacy of present medical facilities, surgical teams, and the availability of artificial hearts. Unlike heart transplants where there is a shortage of donor organs, no shortage of artificial hearts is expected. However, as mentioned previously, the actual physical dimensions of the artificial heart may limit the number of potential candidates.

Facilities and skilled personnel are essential to a successful clinical application of the artificial heart. Existing open heart facilities, which have expanded in the last decade, should be adequate for artificial heart surgery and postoperative recovery. In fact, there may be a need to limit the surgical procedure to a few facilities on a regional basis in order to optimize patient outcome. In January 1984, approximately 20 centers performed heart transplants in the U.S. In the next five years, a substantial increase in the number of heart transplant centers is expected. In theory, these institutions would have sufficient resources for an artificial heart program once personnel are trained in its use. However, this would require a significant investment in time, money, and personnel.

The estimated personnel required for the surgical procedure include: a chief surgeon, an associate surgeon, two anesthesiologists, two heart-lung machine operators, three surgical assistants (in teaching institutions, ordinarily residents), three nurses, two technicians, and an artificial device engineer. In addition, the experience of the surgical teams at the University of Utah and Humana Hospital Audubon indicates that the chief attending physician, an artificial device engineer, and additional support personnel should be available while the patient remains in the hospital in case of device failure, stroke, or other complications requiring immediate attention. The cooperative effort necessary for implantation extends to other hospital personnel, including laboratory technicians, radiologists, therapists, psychologists, and the nursing staff. There is also a need for counseling and education for the patient's family to ensure that they are able to operate the drive system, read and interpret monitoring information, and perform basic medical tasks. Nursing education for the family facilitates the patient's move from the hospital to an intermediate care facility, and eventually to home. If and when the patient does leave the hospital, some form of continuing medical care and nursing supervision will also be required.

DIRECT COSTS

The following discussion of the estimated costs of biventricular replacement per patient and for society includes consideration of: device costs; the costs of initial surgery, including preoperative and postoperative care; and the costs of continuing medical care throughout the patient's lifetime.

Device Costs. Estimates of the cost of the artificial heart vary, depending on the energy source that is used. The Jarvik-7, in use at the University of Utah and Humana Hospital Audubon, relies on an external power source of compressed air and electricity (the 323 pound UtahDrive pump). The Heimes portable (11 pound) rechargeable power pack may be used for up to five hours and can be carried over the shoulder. The cost of the Jarvik-7 heart and pump is estimated at $15,000 for the heart itself, and $30,000 for the console (18).

Symbion, Inc. (manufacturer of the Jarvik-7) is also working on the development of an electrohydraulic device with an implantable pump (18). The current model requires an external battery that may be worn on a belt with percutaneous leads.

Another system under research at the Pennsylvania State University is an electromechanical device with a fully implantable drive (24;30). The device has a rechargeable portable power supply that is carried over the shoulder or around the waist. This portable source needs to be recharged every 10 hours. The power is delivered transcutaneously, eliminating the need for leads from the body. However, clinical trials of this device are not expected for another five years. Estimated costs for this device are $10,000 to $15,000. In addition, the portable battery packs will cost several hundred dollars a year. An alternate, external console for stationary use is estimated at $25,000.

In all cases, there is little potential for declining costs with mass production because of the high level of reliability required and the expensive marketing structure.

Previously, government sponsored programs were directed at a totally implantable nuclear energy source of plutonium 238. However, the cost and the problems of patient and public safety resulting from the significant power requirements, which are several orders of magnitude greater than a nuclear powered pacemaker, pose serious obstacles. Current prototypes of the artificial heart do not feature a radionuclide.

Surgical Costs. The surgical procedure and postoperative care required for artificial heart implantation are similar to cardiac transplants, but instead of possible rejection of the donor organ, malfunctions of system components and treatment related problems, such as stroke, hemolysis, and kidney problems, are of primary concern. The initial four patients with artificial hearts at the University of Utah and Humana Hospital Audubon all developed acute tubular necrosis in the week immediately following surgery (23). Hemolysis was also a common problem for these patients.

An artificial heart patient can expect to be hospitalized for a minimum of four weeks and as long as several months. For elective implantation, costs begin with assessment prior to the procedure. A portion of the initial hospitalization is in coronary intensive care, at the highest cost. To date, the only artificial heart patient to leave the hospital has been William Schroeder, who did so after approximately five months. Schroeder was moved to a hospital-owned apartment within one quarter mile of the hospital, but was subsequently readmitted with a brain hemorrhage. Continuing medical surveillance is required for the patient's lifetime. Even with an improved device, the patient will be required to make periodic visits to the attending physician and maintain regular monitoring of the electrical system.

Costs of the surgical procedure may be estimated from the experience of heart transplant patients. This data was collected for the National Heart Transplantation Study (NHTS) conducted by the Battelle Human Affairs Research Center. Heart transplants cost between $50,000 and $200,000 per person in 1983 dollars. These figures include charges for hospital facilities, pretransplant evaluation, and professional fees, and exclude donor fees. In the NHTS, mean evaluation costs were

$3,700 for a stay of two days, with a lower bound of $2,700 and an upper bound of $5,200. The largest contributing factor to the total cost of cardiac transplantation is the length of in-patient stay, which averages 56 patient days for survivors (17). Average daily costs are $1,279. The first 10 to 30 days after surgery are usually spent in coronary intensive care at the highest service intensity and costs per day ($1,400).

An estimate of $100,000 for the initial surgery (the average cost for heart transplants at Sanford University) is a moderate estimate for initial artificial heart surgery, since it is based on a shorter hospital stay of 59 days (56 days posttransplant plus 3 evaluation days). Barney Clark's charges were $250,000 for a stay of 112 days for his pioneering implant. William Schroeder was in the hospital for 142 days before he was released to an intermediate facility (and subsequently readmitted). Consequently, we will use $250,000 as an upper bound figure based on current treatment. Improvements in design and treatment may reduce the hospitalizations. Under this assumption, we will use a lower bound estimate of $80,000, the mean cost of heart transplants including evaluation. These costs are in 1983 dollars and are significantly higher than our previous estimates (based on 1979 dollars), which ranged from $24,000 to $75,000 per patient (21).

Continuing Medical Care. The figures submitted above are for the initial surgical procedure. After discharge from the hospital, artificial heart patients will require continuous monitoring and yearly expenses for the drive system in use. For those devices where rechargeable external portable battery packs are in use, recipients must recharge and replace batteries. The costs for these battery packs have been estimated at $500 to $1,000 per year. We do not expect the continuing surveillance needs of artificial heart recipients to be less than emergency medical treatment and monitoring costs of cardiac pacemakers, which are approximately $1,500 per patient per year. This figure is based on patients who are monitored twice monthly with four office visits a year. In some cases, continuing pacemaker maintenance costs are as high as $4,000 per year for patients who are monitored with six office visits a year (26).

For air-driven hearts with a stationary console, the costs of running the drive system are approximately $3,000 annually (28). We would expect patients with this type of artificial heart to have follow-up care similar to heart transplant patients. In-patient follow-up care (at the transplant center and other hospitals) for medical surveillance, chest x-rays, lab test, and EKGs is approximately $7,791 in the postdischarge year, and out-patient follow-up care is about $1,744 for a total of $9,535. In the second through tenth posttransplant years, in-patient costs are $4,517 and out-patient costs, $1,744, for a total of $6,261 (17). The higher costs for patients with pacemakers or heart transplants who required additional surgery for reimplantation of the pacemaker or a second heart transplant are not included in these figures.

Summary of Costs. Table 1 contains three estimates of the major expenses incurred in the diagnosis, implantation, and immediate recovery of patients undergoing artificial heart implantation. These items have been discussed in the previous section.

The lower bound cost estimate (A) is based on a portable device with a rechargeable power source at $15,000, a low estimate of $80,000 for the surgical procedure, $1,500 for continued medical surveillance, and $500 for batteries.

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

Item of expense	*A*	*B*	*C*
Implantation			
Surgical procedure and care	$80,000	$100,000	$250,000
Device	15,000	15,000	15,000
Console	–	–	30,000
Continuing care			
Medical care	1,500	4,000	6,300
Batteries	500	1,000	–
Total	$97,000	$120,000	$301,300

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

The middle estimate also is based on a portable device, but we assume higher replacement costs for batteries of $1,000 per year and increased surveillance costs of $4,000 annually. The middle estimate of $100,000 for the surgical procedure is used in this case.

The upper estimate (C) is based on the current hydroelectric device ($15,000), with a stationary power drive ($30,000), and surgical costs of $250,000. The upper bound estimate for continuing surveillance is drawn from the experience of heart transplant patients in the second to tenth year posttransplant.

In Table 2, these projections for the initial year of implantation and continuing medical surveillance are applied to the range of patient pools described in a previous section. Table 2 also shows the impact of the various estimates of implants per year on present facilities and physicians. Even the lowest estimates project a very costly program, equivalent to current annual expenditures for kidney dialysis, which are estimated to be $1.8 billion (15). The estimates in Table 2 are for the initial year of a mass implantation program. As the procedure continues, costs for continuing medical care for survivors will accrue. Based on the actual survival rates for Stanford heart transplant patients after 1980 (28), five-year cost projections are presented in Table 3 for a range of patient populations, a middle estimate of $120,000 per patient for the initial year, and continuing care of $5,000 per patient per year. In year 0, 85% of patients are assumed to survive the procedure, and 75% are assumed to survive after one year. The figures in Table 3 have not been discounted to yield the present value, since the bulk of costs occur in the first year. Continuing medical care contributes very little to total costs. With only 11,500 implantations per year, the program would average $1.3 billion a year. With 32,500 patients, the program will cost approximately $3.8 billion a year; and costs will rise to $7.4 billion per year at the higher patient pool of 64,000 persons per year.

Estimates of Increased Life Expectancy. The annual benefit of artificial heart implantation is the increase in life expectancy due to the postponement of premature death from ischemic heart disease (IHD). Life tables are used here to give a set of "best case" and "worst case" projections regarding delaying death from IHD (10;33). In calculating these projections, I assume that recipients of the artificial heart would have died if the device had not been installed. While this is

Table 2. Effect of Numbers of Artificial Heart Implants on Available Societal Resources

Replacements per year	*Total costs per year ($100,000) with implantation costs of*			*Implants/surgeon/year with number of available surgeons*			*Implants/facility/year with number of available facilities*		
	$80,000	*$100,000*	*$301,300*	*800*	*1,000*	*1,200*	*500*	*650*	*750*
11,500	$ 920.0	$1,150.0	$ 3,464.9	14.4	11.5	9.6	23.0	17.7	15.3
32,500	2,600.0	3,250.0	9,792.3	40.6	32.5	27.1	65.0	50.0	43.3
64,000	5,120.0	6,400.0	19,283.2	80.0	64.0	53.3	128.0	98.5	85.3

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

Table 3. Five Year Cost Projections ($100,000) for Artificial Heart Implantation

	Implants per year		
Year[a]	*11,500*	*32,500*	*64,000*
0	$1,150.0	$3,250.0	$6,400.0
1	1,193.1	3,371.9	6,640.0
2	1,233.4	3,485.7	6,864.0
3	1,269.6	3,588.1	7,065.6
4	1,302.4	3,680.7	7,248.0
5	1,311.7	3,763.6	7,411.2

[a] Survival rates assume a five-year, 51% survival; with 75% survival after one year; 70% survival after two years; 63% survival after three years; 57% survival after four years; and 51% after five years.

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

not completely true (not all patients are on the verge of instantaneous death), the experience of heart transplants indicates that patients who are selected for a transplant die within six months if they do not receive a new heart (17). However, those patients who do not receive an artificial heart and who do not die instantaneously will also receive expensive medical care.

Under my "best case" assumptions, approximately one-sixth of the persons dying of IHD will be candidates for artificial heart replacement. Under the worst conditions, only one-twelfth of patients dying of IHD receive the device. Assumptions regarding mortality for both instances and adjusted for recipients in ten-year age groups, are presented in Appendix 2.

Under the "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 one week). The gain in life expectancy will accrue only to those 25-year-olds destined to develop IHD. Thus, the calculated increase in life expectancy for these individuals is 0.6049 year (best case) and 0.1348 year (worst case). At older ages, the gain in life expectancy becomes smaller; ultimately decreasing to below average for those individuals over 65 years.

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 years (or 25 days). Under the "worst case" conditions, the average increase is 0.0106 years (4 days). For those individuals destined to develop IHD, the average increase is 0.4478 year, or 163 days (best case); and 0.0926 year or 34 days (worst case).

ALTERNATIVE THERAPIES

There are alternative therapies, both medical and surgical, that are designed to lessen the high mortality from ischemic heart disease. These include heart trans-

plants, coronary artery bypass surgery, and heart disease prevention. The potential pool of patients for artificial heart implantation are, for the most part, at a stage where these alternative therapies are no longer applicable. However, to the extent that these procedures or prevention programs can reduce the incidence of end-stage heart disease in the future, the artificial heart may become a more cost-effective procedure. Given current information, direct comparisons of these alternative methods are not possible. However, future assessments of the artificial heart should take into account the societal costs associated with the artificial heart, such as increased Medicare and social security expenditures, and the savings that might accrue due to the availability of the artificial heart, such as savings in terms of other medical care that is no longer necessary.

SUMMARY

As discussed above, approximately 32,500 persons aged 55 to 70 years with end-stage heart disease may be potential candidates for the artificial heart each year. However, continued application of a protocol that requires informed consent by the patient effectively limits the pool to 12,000 annually. Estimates of the cost of the artificial heart include charges for the surgical procedure, device and console, and continuing medical surveillance. These estimates range from a low of $100,000 to a high of $300,000 per patient in the initial year. Assuming a five-year, 51% survival and an initial cost of $100,000, total program costs in the fifth year are projected to be $1.3 billion for a pool of 12,000 patients, and $3.8 billion for 32,500 patients.

These projected costs are associated with anticipated increases in life expectancy. For those individuals destined to develop heart disease, the anticipated average increase is approximately half a year. In comparison, heart transplant patients who meet the surgical criteria but who do not receive a new heart do not survive beyond six months.

In an era of limited resources, it is imperative that such a potentially expensive innovation as the artificial heart be compared carefully with other social and medical programs designed to extend life and improve its quality. Such a comparison will require a full understanding of the likely costs and benefits of the device. A viable artificial heart would greatly alter current treatment for end-stage cardiac disease. More patients would benefit from this therapy than currently benefit from heart transplants, and the costs of caring for these patients would increase substantially. The current state of development of the artificial heart provides an opportunity to collect data on investigational artificial heart performance, clinical results, patient status, and economic and social costs. This knowledge base would be invaluable for future technology assessments and policy decisions regarding third party reimbursement. Insofar as we may be faced with a multi-billion dollar annual investment in the future, detailed assessments of the artificial heart should be performed.

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APPENDIX 1. ESTIMATES OF POTENTIAL CANDIDATES IN THE UNITED STATES, 1982

GROUP 1: PERSONS WHO ARE UNABLE TO COME OFF THE CARDIOPULMONARY BYPASS PUMP

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 200,000 coronary bypass operations and other open heart surgeries are performed yearly. Of the patients undergoing these procedures, between 0.5% and 1.0% are unable to be weaned from the pump. Thus, this group would include 1,000 to 2,000 persons per year.

GROUP 2: PERSONS WITH WORSENING CHRONIC SEVERE HEART DISEASE

Patients with severe cardiomyopathy and electrical instability of the heart must have a class IV medical profile, as defined by the New York Heart Association. These patients are unable to participate in any physical activity without discomfort. The level of cardiac disability is irreversible with conventional therapy. Those patients who survive two or more hours in the hospital, yet have a worsening course, have been estimated at 8,000 to 15,000 persons annually. We will use an estimate of 10,000 such patients per year.

GROUP 3: PERSONS SUFFERING MYOCARDIAL INFARCTION AND/OR CARDIAC ARREST

In 1982, there were 554,900 deaths caused by heart attack. Approximately 50% of these persons die before reaching the hospital. Twenty-five percent die within two hours of the cardiac arrest. Both of these subgroups of patients would not be eligible for artificial heart implantation. Another 16% of surviving patients die suddenly in the hospital without warning. We calculate this group of patients, as follows:

Cardiac deaths/year	554,900
less 50% who die immediately	−277,450
less 25% who die in 2 hours	−138,725
Subtotal: 138,725	
less 16% "sudden death"	− 22,196
Total Estimate Group 3: 116,529	

ALL GROUPS

By combining the estimates presented above, we have a total of 128,529 potential artificial heart candidates of all ages. Applying the estimated prevalence of severe,

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irreversible noncardiac disease (262/1,000) that would exclude potential candidates from consideration, we have 0.262 × 128,529, or 33,674 persons that would be excluded. The exclusion of that group leaves 94,854 candidates of all ages.

MAXIMUM AGE CONSIDERATIONS

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

<55 years	7.6%
<65 years	19.7%
<70 years	42.0%
<75 years	57.5%
<80 years	75.0%

From the application of the proportional distribution of cardiac deaths to the 94,854 candidates of all ages, and excluding 7,209 (7.6%) persons under 55 years of age who are eligible for heart transplants, we derive the following number of candidates:

65 years	11,477
70 years	32,630
75 years	47,332
80 years	63,932

If medical and age criteria limit patients to those less than 70 years, but older than 55 years, there would be approximately 32,500 artificial heart candidates each year. If there are large and intractable problems with the artificial heart, or if there is an upper age limit of 65 years, the pool of potential candidates would be substantially lower. Accordingly, we suggest a lower estimate of 11,500 patients. If the device has improved success and/or if the patient medical and age criteria are relaxed, the middle estimate of 32,500 patients might increase. To allow for this possibility, we submit an upper bound estimate of 64,000 patients per year. These estimates assume that all candidates agree to replacement and have access to hospitals capable of implantation.

APPENDIX 2. ESTIMATES OF INCREASED LIFE EXPECTANCY FOR ARTIFICIAL HEART RECIPIENTS

A set of "best case" and "worst case" assumptions are presented in the following tables. Under the best case, approximately one-sixth of the persons dying of CHD will be candidates for artificial heart replacement. Under the worst conditions, only one-twelfth of patients dying of CHD receive the device. Assumptions regarding mortality for both instances, adjusted for recipients in 10-year age groups, from 25 years to 85 years are presented in Table 2.1

A new net distribution of death due to ischemic heart disease that results from the availability of the artificial heart is then calculated. This process assumes that individuals can die in each 10-year age interval from three sources: first, they may

Table 2.1. Fraction of Patients Obtaining the Artificial Heart Who Die Due to Device Failure at Subsequent Ages

Age at which device failed	*Age at which device was obtained best case*[a]				
	0–24	*25–34*	*35–44*	*45–54*	*55–64*
0–24	0	0	0	0	0
25–34	0	.15	0	0	0
35–44	0	.30	.20	0	0
45–54	0	.30	.35	.25	0
55–64	0	.25	.35	.40	.30
65–74	0	0	.10	.30	.45
75–84	0	0	0	.05	.25
85 and over	0	0	0	0	0
Age at which device failed	*Age at which device was obtained worst case*[b]				
	0–24	*25–34*	*35–44*	*45–54*	*55–64*
0–24	0	0	0	0	0
25–34	0	.30	0	0	0
35–44	0	.60	.40	0	0
45–54	0	.10	.60	.50	0
55–64	0	0	0	.50	.60
65–74	0	0	0	0	.40
75 and over	0	0	0	0	0

[a] Best case assumes that 1/6 CHD population receives the device.
[b] Worst case assumes that 1/12 CHD population receives the device.

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Table 2.2. Increase in Life Expectancy in Years for Randomly Selected Individuals by Age

				Age					
0–4	*5–14*	*15–24*	*25–34*	*35–44*	*45–54*	*55–64*	*65–74*	*75–84*	*85+*
Best case									
.0960	.0963	.0966	.0977	.0963	.0804	.0306	−.0602[a]	−.0137	0.0
Worst case									
.0214	.02146	.0215	.0218	.02096	.0151	.0011	−.019	0.0	0.0

Best case = 1/6 IHD population receives the device.
Worst case = 1/12 IHD population received the device.
[a] Negative values are explained in the test.

Table 2.3. Increase in Life Expectancy in Years for Individuals Destined to Develop IHD by Age

				Age					
0–4	*5–14*	*15–24*	*25–34*	*35–44*	*45–54*	*55–64*	*65–74*	*75–84*	*85+*
Best case									
.6025	.6029	.6033	.6049	.59085	.4925	.1935	−.4287[a]	−.1430	0.0
Worst case									
.1343	.1344	.1345	.1348	.1285	.0925	.007	−.1342	0.0	0.0

Best case = 1/6 IHD population receives the device.
Worst case = 1/12 IHD population received the device.
[a] Negative values are explained in the test.

die from CHD because they failed to receive the device; second, patients might die due to complications associated with an artificial heart received earlier, or individuals may die from other causes. This new net distribution of time to death is then compared with age-specific deaths from CHD in 1979, and used to calculate the increase in life expectancy that might be enjoyed by a randomly chosen member of the U.S. population. These increases are presented in Table 2.2.

Under the best care assumptions, a randomly chosen 25-year-old gains .0966 of a year (approximately 35 days) in life expectancy. Under the worst case assumptions, the gain is reduced to .0215 of a year (about seven days). At older ages, the gain in life expectancy *declines* because these persons have a much shorter period of time in which to become candidates. For cohorts above age 65, there is a loss in life expectancy, because these persons are themselves ineligible for the artificial heart. As a result, they suffer a decreased longevity, because the age category also includes individuals who received the device prior to age 65 and who bear the added risk of future complications. In a similar fashion, the gain in life expectancy for individuals in 10-year cohorts who are destined to develop coronary heart disease is shown in Table 2.3.

The population average, adjusted for the proportion in each age group, is then calculated. Under the best case conditions, the average increase is .0697 years (about 25 days) for the general population. Under the worst case conditions, the average increase is .0106 years (four days). For these individuals destined to develop ischemic heart disease, the average increase for the best conditions is .4478 years (163 days) and .0926 years (34 days) under the worst conditions.

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