

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 pre-implantation 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 10-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

**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

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).

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  $f_i$  of those who develop IHD in their  $i^{\text{th}}$  age interval gets the device (see table 6). We also supposed that a proportion  $r_j$  of those getting the device in interval  $j$  dies due to complications associated with the device in a subsequent interval  $i$ ,  $i \geq j$ . The proportions  $r_j$  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  $i^{\text{th}}$  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-

\*See discussion above on the pool of potential recipients.

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

Age at which device failed	Age at which device was obtained						
	0-4	5-14	15-24	25-34	35-44	45-54	55-64
0-4 . . . . .	0	0	0	0	0	0	0
5-14 . . . . .	0	0	0	0	0	0	0
15-24 . . . . .	0	0	0	0	0	0	0
25-34 . . . . .	0	0	0	0.15	0	0	0
35-44 . . . . .	0	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 failed	Age at which device was obtained						
	0-4	5-14	15-24	25-34	35-44	45-54	55-64
0-4 . . . . .	0	0	0	0	0	0	0
5-14 . . . . .	0	0	0	0	0	0	0
15-24 . . . . .	0	0	0	0	0	0	0
25-34 . . . . .	0	0	0	0.3	0	0	0
35-44 . . . . .	0	0	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: *Monthly Vital Statistics Report* (Hyattsville, Md.: National Center for Health Statistics).

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

Age	Death rate
0-4 . . . . .	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 Vital Statistics Report* (Hyattsville, Md.: National Center for Health Statistics).

suit of complications associated with a device received in a previous interval  $j \leq i$ . 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 Randomly 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

<sup>a</sup>Negative 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, 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

<sup>a</sup>Negative 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, McKegney, 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