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.

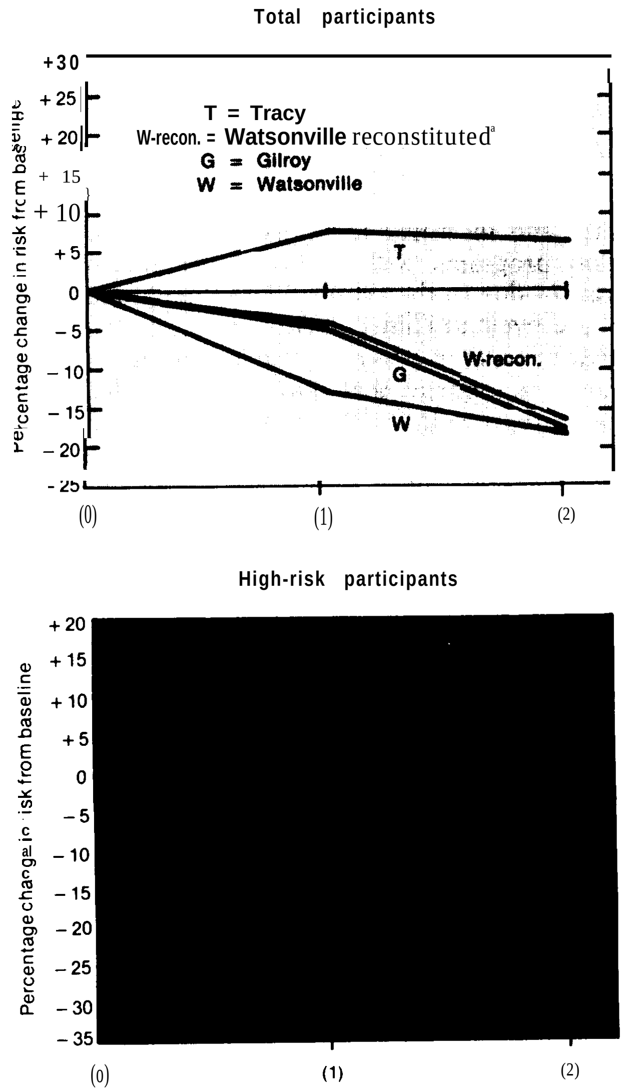
The evidence establishing a constellation of risk factors related to coronary heart disease (CHD) led NHLBI in 1970 to fund several decade-long, community-based clinical trials designed to develop methods of risk reduction applicable to home, work, and community environments. The Stanford Heart Disease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

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