

A REVIEW AND ANALYSIS OF THE UTILIZATION OF ARTIFICIAL HEARTS IN MANKIND^{1, 2}

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ABSTRACT

Research by the authors and expert opinion obtained from interview and questionnaire response predict the availability of an acceptable artificial heart for use in humans, and the development of proper medical procedures for its installation, within the next 15 to 20 years. Present medical advances are reducing the number of heart problems solvable by artificial-heart implantation, but, because of increasing population, the actual number of those needing this operation may not decrease.

Application of a least-squares straight-line trend to the present number of physicians in the United States leads to an increase in future numbers of physicians which is not quite equal to the population increase. However, with the relative simplicity of this type of operation compared to other heart operations, the availability of highly specialized heart-care medical centers, and the provision of several supporting surgical teams per physician, heart-implant operations should be available to all who need them. Such operations would not be cheap (estimated to cost \$5-6,000 for the artificial heart and \$5-50,000 for the implantation), but this should not deter use of the operation when survival is at stake. Given the availability of a reliable artificial heart, its successful use in mankind appears extremely optimistic if the required planning and research are performed.

INTRODUCTION

Modern methods of forecasting technology and resultant predictions have made possible more effective long-range planning and analysis and also better adaptation to conditions which deviate from forecasts and plans. The important contribution of forecasting technology is that it makes possible identification and estimation of trends toward future conditions, such as projected demand for and projected availability of financial resources, facilities, and manpower. These estimates provide the basis for advance planning, which facilitates the more rapid and effective application of the results of research toward and development of the artificial heart. Such an artificial heart is predicted to become available within the next two decades, despite the many problems yet to be solved through research and development.

Heart disease today claims some 700,000 to 1,000,000 Americans yearly, according to both Colenpaul (1971) and Harmison (1972). Estimates vary as to how many or what percent of heart-disease deaths could have been avoided or postponed by utilization of an artificial heart. Cooper (1972) estimated that from 10,000 to 100,000 Americans might be potential candidates for artificial hearts when they become available; Harmison (1972) has estimated the demand to be between 15,000 and 100,000. The authors of this paper recognize that mortality statistics are primarily an estimate at the present time, but such statistics still provide a starting point for this analysis. It is also recognized that the estimated demand (by Cooper, 1972, and by Harmison, 1972) for an artificial heart might be vastly overestimated, but it is proposed that there is and will continue to be a very real and significant demand for an artificial heart. The fact that this demand

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³The two nonmedically trained authors believed that the viewpoint of a thoracic surgeon was required to evaluate the validity of the premises and research findings. Dr. Vasko provided this input and agreed to be listed as a coauthor. In order to identify his medical views, in contrast to the views of the two nonmedical authors, Dr. Vasko's name is used in the text with his contributions.

cannot presently be stated with a high degree of certainty should not be used as a basis for not considering and understanding the nature of the factors necessary for the timely and effective utilization in man of an artificial heart, when it is available.

Information about the actual research and development of the artificial heart itself is not analyzed in this paper. This paper reviews and analyzes the factors basic to the planning and control of a program designed to insure timely and effective utilization of artificial hearts by mankind.

RESEARCH METHODS

Research for this paper was begun by reviewing relevant literature and government publications. Then copies of Delphi-type questionnaires were sent to

TABLE I
List of experts to whom Delphi questionnaire was sent¹

Dr. Michael DeBakey College of Medicine Baylor University Houston, Texas	Med. Services Applications Br. 9000 Rockville Pike Bethesda, Maryland Dr. F. N. Huffman
Dr. P. L. Blackshear Department of Mechanical Engineering Institute of Technology University of Minnesota Minneapolis, Minnesota	Therme Electron Research and Development Center 85 First Avenue Waltham, Mass.
Dr. T. Akutsu Department of Surgery University of Mississippi Medical Center Jackson, Mississippi	Dr. A. Kantrowitz Department of Surgery Maimonides Medical Center 4802 Tenth Avenue Brooklyn, New York
Dr. V. L. Gott Department of Surgery School of Medicine Johns Hopkins University Baltimore, Maryland	Dr. Richard R. Lower Department of Surgery The Medical College of Virginia Richmond, Virginia
Dr. Cominge Liotta Texas Heart Institute Texas Medical Center Houston, Texas	Dr. Denton A. Cooley Texas Heart Institute Texas Medical Center Houston, Texas
Dr. Y. Nese Department of Artificial Organs Cleveland Clinic Foundation 9500 Euclid Cleveland, Ohio	Dr. Frank Hastings Artificial Heart Program National Heart and Lung Institute 9000 Rockville Pike Bethesda, Maryland
Dr. C. S. Kwan-Gett Division of Artificial Organs Department of Surgery College of Medicine University of Utah Salt Lake City, Utah	Dr. Willem Kolff Division of Artificial Organs College of Medicine University of Utah Salt Lake City, Utah
Dr. L. T. Harmison National Heart & Lung Institute	Dr. Donald Lyman University of Utah Salt Lake City, Utah

NOTE: It is not to be construed that these are the only or the main experts in this area, but only that it was these particular individuals that were solicited to participate in this survey as experts in the area of heart research

¹Of these 15 experts, 9 responded, but because the replies were anonymous, the identities of the nine respondents are not known.

fifteen experts in the area of heart research. These persons were asked to respond anonymously. (The Delphi technique involves the use of a questionnaire which is designed to enable a forecast to be made as the result of the systematic solicitation of expert opinion.) Nine of the fifteen experts solicited are shown in table 1. Because the questionnaires were not marked in any way and because the replies

were anonymous, as requested, the identities of the nine who responded are not known. Replies are summarized in table 2.

John S. Vasko, M.D., University Hospital, The Ohio State University, Columbus, Ohio, provided extensive expert medical opinion and analysis. He is intimately involved in the field of heart surgery and is familiar with the implications for utilization of an artificial heart. Because of the extent of his contributions, Dr. Vasko agreed to be listed as a coauthor of this paper.

Review and analysis of a subject like the development and use of an artificial heart is highly subjective at this time and does not necessarily produce statistically reliable conclusions because of the inherent nature of this subject area. However, it is still very important to review the nature and status of the various factors, as best determined from the above sources, in order to recognize and understand how they may affect the utilization of the artificial heart. The analysis of these factors, plus advance planning, will enable an earlier utilization of the artificial heart than would be possible if no planning were done until the time when the artificial heart is finally perfected.

TABLE 2

Summary of responses of respondents participating in Delphi questionnaire survey¹

DELPHI QUESTIONNAIRE

The permanent, implantable, totally artificial heart

1. In your opinion when will an implantable internal power source be available that is suitable for use with the artificial heart and
 - a. will give approximately 1 year of service?
 - 5 (1) already has been developed.
 - 2 (2) within the next 5 years.
 - 3 (3) within the next 10 years.
 - 4 (4) within the next 15 years.
 - 5 (5) will never be developed.
 - 6 (6) other (please specify) _____
 - b. will give 10 years or more of service?
 - 1 (1) already has been developed.
 - 2 (2) within the next 5 years.
 - 4 (3) within the next 10 years.
 - 4 (4) within the next 15 years.
 - 5 (5) will never be developed.
 - 6 (6) other (please specify) _____
2. When do you feel an acceptable antithrombogenic material will be developed and refined to such a degree that it could be used in the artificial heart and
 - a. give 1 year of service?
 - 3 (1) already has been developed.
 - 4 (2) within the next 5 years.
 - 2 (3) within the next 10 years.
 - 4 (4) within the next 15 years.
 - 5 (5) will never be developed.
 - 6 (6) other (please specify) _____
 - b. give 10 years or more of service?
 - 1 (1) already has been developed.
 - 1 (2) within the next 5 years.
 - 4 (3) within the next 10 years.
 - 3 (4) within the next 15 years.
 - 5 (5) will never be developed.
 - 6 (6) other (please specify) _____
3. In your opinion when will a temporary heart-assist device that can aid circulation for up to three months be developed?
 - 4 (1) already has been developed.
 - 5 (2) within the next 5 years.
 - 3 (3) within the next 10 years.
 - 4 (4) within the next 15 years.
 - 5 (5) will never be developed.
 - 6 (6) other (please specify) _____

TABLE 2—(Continued)

DELPHI QUESTIONNAIRE

The permanent, implantable, totally artificial heart

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4. In your opinion when will an artificial heart be developed and put into use that will have a 95% reliability and
- a. will give 1 year of service?
 - 5 (1) already has been developed.
 - 2 (2) within the next 5 years.
 - 2 (3) within the next 10 years.
 - 2 (4) within the next 15 years.
 - (5) will never be developed.
 - (6) other (please specify) _____
 - b. will give 10 years or more of service?
 - 1 (1) already has been developed.
 - 3 (2) within the next 5 years.
 - 5 (3) within the next 10 years.
 - (4) within the next 15 years.
 - (5) will never be developed.
 - (6) other (please specify) _____
5. Using 1973 dollars, please estimate the cost of implantation of a permanent totally artificial heart in the 100th patient to receive such a device.
- (1) less than \$3000.
 - 3 (2) \$3000-\$5000.
 - 5 (3) \$5000-\$10,000.
 - 1 (4) \$10,000-\$20,000.
 - 1 (6) other (please specify) _____
6. What % of individuals in the U.S. dying from heart disease each year could have their lives prolonged using the totally artificial heart (permanent)?
- 3 (1) less than 10%.
 - 2 (2) 11%-20%.
 - 1 (3) 21%-40%.
 - 1 (4) 41%-60%.
 - 2 (5) 61%-80%.
 - (6) 81%-100%.
7. Do you think that the federal government will develop a national health program that would provide this device at a nominal charge to the public?
- 8 (1) yes. If yes, in what year would such a program be in operation? 1980's.
 - 1 (2) no.
8. Do you personally think that devices such as this one will ever outperform (in terms of number of malfunctions, estimated length of service) the natural organ it replaces?
- 2 (1) yes. If yes, in what year would this be achieved? 1977, 1993.
 - 7 (2) no.
9. In your opinion, will use of the artificial heart ever completely replace the use of human transplants?
- 3 (1) yes. If yes, in what year do you think this will occur? 1974, 1985.
 - 5 (2) no.
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¹A systematic tabulation of the responses of the 9 experts, out of the 15 solicited, who responded anonymously to the questionnaire.

RESULTS AND DISCUSSION

The future availability of a reliable artificial heart is not totally agreed upon by experts in the field, probably because of the large amount of research remaining and the funding still required for this research. Responses to question 4 in the Delphi questionnaire (table 2) do indicate that all nine respondents believe that an artificial heart with a 95 percent reliability factor which will give 10 years or more of service will be available within the next 15 years, although four of them feel it will be available sooner. The reality of an artificial heart in the future is a "fact of life" according to Dr. Vasko, and he concurs with the the respondents to the survey that it will indeed be available within 15 years. However, he recognizes that extensive research and development are still required in the areas

of materials, autoregulation, power source, reliability, durability, and the size of the whole artificial heart. In addition, after it becomes available, Dr. Vasko feels that there will first be a period of limited use, followed by gradual expansion of use through controlled clinical trials.

The demand for artificial hearts during the next 15 to 20 years and beyond is extremely difficult to estimate, because of potential progress that may take place in medical technology that is unknown at this time. For example, Dr. Vasko feels that a significant decrease in the incidence of congenital heart lesions is occurring at the present time, and that some progress is being made in the reduction of degenerative heart disease. The use of pacemakers and the application of coronary-artery-bypass graft procedures are other techniques which have the potential of reducing the demand for the artificial heart. Further development of preventive medicine may significantly reduce arteriosclerosis and various cardiomyopathies (the cardiac-muscle disorder usually produced by infectious processes or autoimmune reactions); this might also reduce the demand for artificial hearts.

The population of the United States in 1971 was 207,049,000 persons, and estimates indicate an increase to 322,000,000 by the year 2000 (Statistical Abstract of the United States, 1972). Therefore, the potential decrease in the number of deaths caused by heart disease, as discussed above, may be offset by the growth in population; *i.e.*, more individuals may require an artificial heart for survival as the total population size rises. Other potential factors affecting demand may become known by the time the artificial heart is perfected and implant and performance experience is obtained. Dr. Vasko feels that the implant of an artificial heart will be a simpler surgical procedure than are many present heart operations. Therefore the use of artificial hearts with proven high reliability may be preferable to other more complex surgical procedures.

The use of an artificial heart implant will have to be evaluated on the basis of the cost of the procedure compared to the cost of alternative procedures (a cost-benefit type of analysis). Although the cost is difficult to estimate with any reliability, Cooper (1972) estimated the cost of an artificial heart to be between \$5,000 and \$6,000 and the cost of the implant operation to be from \$5,000 to \$50,000. Dr. Vasko, however, feels that the cost of the implant operation would be less than Cooper's estimate because of the simpler surgical technique involved.

A significant increase in the Federal government's support of medical care is reflected in the Standard and Poor Industrial Survey (1973), a trend that can be expected to continue in our present social environment. The U.S. Industrial Outlook (U.S. Government Printing Office, 1972) estimates that the gross national product will be 1,400 billion dollars in 1975 and nearly 2,000 billion dollars in 1980; the authors estimate that it will be approximately 3,000 billion dollars by the year 2000. All of these estimates are in current dollars. In addition, as the Gross National Product rises along with population growth, the authors predict, on the basis of the availability of a higher tax base and society's increasing demand for medical care for all, still further Federal government participation in health care. Obviously, there will be compromises between the types of care that will be available and the mechanisms (types of national health-insurance plans) used to finance this concept. But the expense of an artificial heart implant, where required for a patient's survival and return to an acceptable life style, becomes less important when survival is considered. When a reliable artificial heart is available, the authors feel strongly that those requiring it will be able to receive the implant operation, regardless of personal finances.

Another major factor in the utilization of artificial hearts will be the availability of surgeons to perform the implant operations. The number of physicians in the United States from 1963 through 1969 is shown in table 3. Using these data, a least-squares straight-line trend was estimated for the years 1970 through 1975. Based on this, it was calculated that the number of available physicians

TABLE 3
Number of physicians in the United States

Year	Number ¹
1963	289,200
1964	297,100
1965	305,100
1966	313,600
1967	322,000
1968	Data not available
1969	338,400

¹Rounded to nearest hundred. Data from Statistical Abstract of the U.S. (1968, table 86, p. 66, and table 95, p. 68).

would increase by 8,240 each year (table 4). However, the percent of growth, using this projection, will decrease, unless there is a rise in the absolute number of trained physicians, *i.e.*, the growth rate in 1969 was $\frac{8,240}{338,400}$ or 2.4 percent whereas the growth rate predicted for 1975 is projected to be $\frac{8,240}{387,800}$ or only 2.1 percent. Although this suggests a decrease in the rate of increase in the number of physicians, the authors see no basis, at present, to predict a shortage of qualified surgeons, especially when the increasing use of highly specialized medical-care delivery centers and the potential advancements in medical technology are considered.

TABLE 4
Estimated number of physicians in the United States

Year	Number
1970	346,600
1971	354,900
1972	363,100
1973	371,400
1974	379,600
1975	387,800

¹Rounded to nearest hundred. Estimates calculated by least-squares straight-line-trend technique.

Dr. Vasko predicts that there is and will continue to be a shift to the use of large heart medical centers which are designed to provide more efficient delivery of highly specialized heart care. Although he has noted a decline in the number of surgeons being trained in cardiothoracic specialties, he feels that the use of highly specialized health-care delivery facilities for heart surgery offsets this decline in cardiothoracic surgeons. Such specialized facilities better utilize the capabilities of present and future surgeons; *i.e.*, one heart surgeon can provide more service in a highly specialized facility than he could in an unspecialized facility. If the demand for artificial heart implant surgery were added to the present demands for heart and other surgery, there might be a tendency to predict a shortage of qualified surgeons. However, the authors feel that this shortage is not probable unless there is a significant downward change in the trend of available physicians

and surgeons, as previously discussed. Because the supply of surgeons versus the demands for their skill is extremely critical to a modern health-delivery-care system, this should be a subject for periodic review.

Another major factor affecting the future demand for surgeons will be advancements in medical technology. Dr. Vasko predicts that the total demand for surgery and surgeons will decrease as a result of advancements made in medical technology; such advancements will direct the emphasis toward preventive medicine rather than toward surgery. An example of this is the significant decrease in the requirement for tuberculosis surgery within recent years. Dr. Vasko feels that the demand for surgeons will decrease even more significantly when a cure for cancer is available. Qualified surgeons can then easily be trained to perform surgery for the implant of artificial hearts.

Medical facilities are another critical factor in the utilization of artificial hearts. Today there is a trend toward highly specialized and very expensive medical facilities, which will have a much higher utilization rate than most of the present medical facilities. Most hospital surgical facilities operate on a schedule from 8 a.m. to 4 p.m., with only emergencies handled at other times. The capability to expand surgical capacity exists simply by adding multiple shifts (assuming the availability of qualified staff). Another alternative for increasing capacity is to have several surgical teams trained and available to support one surgeon. The time and expense required to train and develop a supporting surgical team is much less than that required to train and develop an experienced surgeon. Instead of having long time intervals between surgical operations while operating rooms and supporting teams are prepared, the operating surgeon could immediately proceed to another operation if the additional surgical teams were available. With sufficient planning and organization, added surgical capability (surgeons, supporting team, facilities) for delivery of more health care could rapidly be made available to meet the demand.

SUMMARY AND CONCLUSIONS

Technological forecasting procedures have been used to estimate trends in future population size, in the future availability of physicians and surgeons, and in future facilities. These are three key factors which are highly relevant to the utilization of the artificial heart in mankind. These estimates reflect no major problem. If there is a change in any of the factors discussed in this paper, a reassessment must be made, because of the long lead times required to have available, when needed, sufficient resources, particularly trained and experienced surgeons, other supporting personnel, and to a lesser extent, adequate facilities.

It is the opinion of the authors, and also of the nine respondents to the Delphi questionnaire, that there will be both an artificial heart and implant procedures available in the future, most likely within the next twenty years. Because a certain proportion of heart patients in the future will survive only by implantation of an artificial heart, research and analysis should begin now by analyzing present heart cases to identify those for whom artificial hearts might have greater benefit than present heart-surgery methods, either presently available or predicted. It must be recognized that the artificial heart is not a therapeutic panacea for all heart disease; other methods of treatment might be developed which are superior in some cases. Knowledge and experience should be gained so as to identify cases where implantation of an artificial heart will produce the greatest benefit. This could aid in reducing the period of controlled clinical trial when the artificial heart becomes a reality.

By the time a reliable artificial heart is available, the authors conclude that there will be an adequate demand, a supply of competent surgeons to perform the implant operation, appropriate facilities of a highly specialized nature, and funds available through some type of individual and/or government-sponsored

medical-insurance plan to cover the costs of the operation. The critical factor now is the allocation of sufficient funds and effort to insure continued progress in the research and development of the artificial heart itself for benefit of mankind and to encourage medical doctors and surgeons to study in these directions.

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