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News
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****Ethics committee releases report on
societal impact of artificial heart.**

DALLAS--Replacing body parts with machines has long been the subject of medical scientists' imaginations. In the past few decades, however, technology has allowed some of those ideas to grow into reality.

For many reasons, an especially attractive and challenging idea has been to replace a failing heart with an artificial one. However, "before this technology achieves an (undeserved) momentum of its own when it would be difficult to stop widespread clinical use, based on only partial clinical success, it's important to see what the impact, including long range effects of this technology might be," says Dr. Robert Eberhart, chairman of the Joint Program in Biomedical Engineering at The University of Texas Health Science Center at Dallas and at UT Arlington.

To study such effects, the National Institutes of Health established an expert committee, on which Eberhart served, to study the issue. The 13-member team consisted of surgeons, cardiologists, bioengineers, ethicists, health economists and patient relations experts. They studied the potential impact of total artificial heart and ventricular assist devices on society. Their report, "Artificial Heart and Assist Devices: Directions, Needs, Costs, Societal and Ethical Issues," was submitted to Claude Lonfant, director of the National Heart, Lung, and Blood Institute, unanimously approved by the Cardiology Advisory Committee, and released to the public on May 25.

Based upon an 18-month investigation, the committee made the following recommendations:

Development and evaluation of the artificial heart -- specifically fully implantable, untethered assist devices as well as the total artificial heart -- should continue. A fully implantable long-term circulatory assist or total artificial heart could lead to a significant (up to four years) increase in life span with an acceptable quality of life, for 17,000 to 35,000 patients annually. The group says that the present clinical system is "importantly suboptimal," since it does not permit sufficient normal activity and requires two compressed air lines which cross the chest wall. "There are other mechanical assist devices being developed now of superior design that will considerably improve the quality of life for the patient, compared to the present model," says Eberhart.

Use of the mechanical circulatory support system, or MCSS (a generic term including any device that supplements or takes over the entire pumping function of the heart), at this time should still be considered investigational, and therefore, be closely monitored.

Public funds for the clinical use of artificial hearts should not be available until they have proved both patient-effective and cost-effective.

Cost-effectiveness and cost-efficiency are essential considerations. No procedure should be used if the benefits are not worth the costs. There must be no other procedures for the same condition that are as or more effective and are of lesser or equal expense. The unanswered question raised by the committee is "where will the money come from?" Says

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Eberhart, "There aren't enough dollars to go around and a choice has to be made as to which medically needy group gets the money." On the other hand, it's argued that a price can't be put on human life. However, cost-efficiency considerations must be put into practice if increasingly expensive new medical therapies continue to be introduced to a society which demands a cap on health care expenditures."

Even when MCSSs are clinically available, their use should be restricted to expert groups whose experience, training, resources and commitments are clearly evident. Dr. William de Vries, surgeon at the Humana Heart Institute in Louisville, Kentucky, and one of only two surgeons FDA-authorized to implant artificial hearts, recently noted that managing one artificial heart patient for the first three months after surgery requires a staff including two surgeons (who will be virtually unable to handle any other patients for this period), numerous specialty medical consultants, 20 nurses, three artificial heart technicians, and the part-time services of a psychologist -- to deal with the staff, not the patient!

Society must be presented with a balanced view of MCSSs so that it can anticipate the problems and failures that will be encountered, as well as the successes. The report states that "the artificial heart must prove itself to society and not immediately be hailed miraculous or life-saving. It is important to caution against the expectation of a medical miracle. This technology will become beneficial, effective and safe only slowly and through experience, with inevitable tragic failures."

Patient suitability criteria must be carefully examined and followed. Present indications specify patients who have a Class IV cardiac disability (a bed-to-chair existence) and no chance of being helped by other surgical or medical treatment. The patient must also exhibit a will to live, the strength to endure stress and the capacity for medical compliance. It is imperative that patients have a supportive network of family or friends and a stable environment for rehabilitation.

Privacy of the patient and family must be respected. No patient should be excluded from selection on the basis of unwillingness to make personal or private information available to the public and the patient should be informed that this choice exists.

Research results should be presented through national scientific meetings and peer-reviewed journals.

Regarding societal and ethical impact, the report made a number of comments. "It is not enough to justify the introduction of the artificial heart by asserting that it will save lives. The burdens its introduction will impose on other lives must also be considered." How will the recipient interact with society or with family and friends? How will everyone concerned (patient, family, friends, employers) deal with the anxieties and dependencies associated with an artificial heart?

It's possible that society may begin to realize that this innovation could bring disadvantages. An emotional and ethical issue of importance to society as a whole is to determine the justification for sustaining a biological life that is essentially unrewarding and negative for the patient. The report says, "We must face the possibility that some individuals who accept the artificial heart with clear awareness of its implications may later choose to discontinue its use." Will this act, or refusal to accept an implantation at all, be considered suicide?

There should be a favorable balance of risks and anticipated benefits. This is complex because the risks are borne by the subject while the benefits may be to the subjects or to society or to both. The patient, nevertheless, must be able to give informed consent after understanding the alternatives, risks, discomforts, economic

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consequences and freedom to withdraw without prejudice.

The committee notes that the artificial heart will gain its first step toward acceptance when it significantly extends the life of human beings doomed otherwise to die. The committee hopes that the fully implantable MCSSs slated to be available for clinical trial within two or three years, will provide at least two years of a reasonably good quality of life, and with further development, at least five years of life that includes normal ambulatory activities and moderate exercise.

Although favoring the further development and use of the artificial heart, the reports says this therapy will pose serious problems to society from the standpoint of cost, distributive justice and patient selection. Society, it says, has a right and an obligation to assess its limitations. The hope remains, however, that the benefits of such a technique will far outweigh its burdens and complications.

"Bill Schroeder, Murray Haydon and Leif Stenberg are alive. They would probably all be dead by now if it weren't for this procedure," says Eberhart. "And yet medicine and technology have a long way to go before artificial hearts are perfected enough to provide a life style that the medical profession and society would wish upon anybody."

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