Statement on Heart Transplantation*

The initiation of clinical heart transplantation has attracted a degree of interest both within the medical profession and among the lay public seldom equalled by any new development in medicine. This interest has taken the form of a continuing debate and discussion as to the medical, ethical, moral, and legal aspects of heart transplantation. This continuing debate within the medical profession, in the public press, and in legislative councils can vitally affect not only the practice of organ transplantation but the form and pace of medical progress. In view of the importance clinical heart transplantation has assumed, not only as a possible therapeutic technique for certain forms of advanced heart disease but as a focal point for larger questions regarding physician responsibility, the nature and determination of death, the protocol of clinical investigation, and the direction of future medical research, the American Medical Association recognizes the preservation of good medical practice demands that the evolution of therapy be orderly.

Surgical skill to perform a cardiac transplant is not enough to justify a program of heart transplantation. The staff of a hospital or medical center planning to initiate such a program should have (1) adequate background in animal research so that experience is gained as to the problems, potentials, and limitations of cardiac transplantation; (2) experience in immunosuppressive therapy and an adequate source of antilymphocyte globulin of known quality; (3) a protocol of clinical research adequate to follow and evaluate the course of the patient. The need for knowledge about the short- and long-term effects of heart transplantation is critical, and to fail in this third requirement is to do a disservice not only to the patient but to medicine. To facilitate the collection and dissemination of scientific information it is recommended that there be established within the United States a Heart Transplant Registry as a means of facilitating the exchange of information among investigators and as an aid to mutual cooperation among the various medical centers.

2. Due regard for the welfare and safety of each individual patient is paramount in the initiation of any new mode of therapy. Risk is unavoidable. But the risk is permissible when the limitations of accepted therapy impose alternatives which, in the informed view of the patient and the best judgment of his physician, justify the risk.

Initiation of human heart transplantation has been criticized by some as premature. The critics maintain that immunosuppressive techniques are not of an order to justify use in a patient of uncertain prognosis a procedure for which there is no alternative means of life support should the procedure fail. In the opinion of others, the experience and knowledge gained in the animal laboratory—an indication, for example, that the transplanted heart can function for extended periods—justify its investigative use in patients in imminent danger of death from progressive congestive heart failure.

This question can be resolved now only by the evaluation of the long-term results of human heart transplantation.

Until such evaluation is possible, the procedure must be regarded as investigative. Its use should be restricted to patients for whom there is no other means of therapy offering a life-sustaining prognosis. The best medical care of the potential recipient demands that he be carefully evaluated. When de-
sirable, those responsible for the patient’s care should seek consultive opinion independent of the transplantation team.

It is well established that the transplanted heart can and usually does function in the postoperative period. This initial success must not be cause for undue optimism about the long-term results, nor does it warrant extension of the procedure to patients in whom it might be regarded as palliative or preventive rather than lifesaving.

3. Heart transplantation has brought certain medical, ethical, and legal questions into critical focus. Paramount among them is the determination of death. The right of the prospective donor to the best possible medical care—a right which his potential role as organ donor must not be allowed to abrogate—must remain sacred. The growing ability of medical science to maintain some form of biological function for prolonged periods adds to the difficulty of defining the point of irreversible dissolution. The cause of death must be evident and be of an irreversible type. The fact of death must be established by adequate, current, and acceptable scientific evidence in the opinion of the physicians making the determination.

The determination of death in organ donors must be made by no less than two physicians not associated with the surgical team performing the transplant.

4. The potential for heart transplantation, whatever that may prove to be by subsequent clinical experience, will be severely limited by the shortage of potential organ donors. The disparity between need and supply in organ transplantation is not limited to hearts, although it represents the widest imbalance, but characterizes all organ transplant programs.

To alleviate the shortage of transplantable organs, the following is recommended: (1) adoption by the appropriate legislative bodies of the Uniform Anatomical Gift Act or similar laws to facilitate the donation of organs and to remove the confusion and medicolegal problems generated by conflicting laws in the several states; (2) initiation in centers where organ transplants have been accomplished or contemplated of cooperative donor organ programs to insure the best possible match between donor and recipient, bearing in mind that the evaluation of this match ultimately depends upon the best clinical judgment of the physicians involved.

It must be recognized, however, that there will never be sufficient numbers of human organs available to meet the potential demand for transplants. Research must continue into methods of organ storage and into development of artificial hearts and cardiac assistance devices. The feasibility of using xenografts must also be explored. Surgical repair of the diseased heart has undergone significant advances in recent years. The possibilities for further advances should be vigorously pursued. Basic research into the causes of heart disease and of hypertensive vascular disease is also of vital importance, since the only ultimate solution to the problem of heart disease lies in its prevention.

5. Human heart transplantation has been accompanied from the outset by a degree of public awareness and attention almost without parallel in medicine. Whereas some would prefer that publicity be withheld until the procedure is properly evaluated in approved scientific fashion, this has become impossible as regards heart transplantation. The dramatic overtones attendant upon the procedure and the seriousness of heart disease as a health problem combine to generate keen public interest.

This publicity poses special questions for the medical profession. The use of public news media for self-seeking purposes on the part of any physician has always been considered unethical. In view of the popular interest aroused by heart transplantation, those most immediately involved must be particularly careful to refrain from any conduct which could be construed as violating these ethical commitments. There is no place in medicine for rivalry for public plaudits.

In addition, public misunderstanding about the nature of clinical investigation, impatience with the need for cautious use and prolonged evaluation, and the disappointment and reaction that could follow should clinical experience indicate that heart transplantation is of limited value could seriously affect established procedures for the introduction of any new mode of therapy.

It is imperative, therefore, that the public be made fully aware of the potentialities and limitations of heart transplantation as those are currently understood and as that understanding is modified by subsequent experience. Moreover, the opportunity should be taken to acquaint the public with the problems attendant upon the introduction of new means of treatment and the rationale for the protocol that is followed. Only by preserving public confidence in the judgment of the physician can the orderly progress of medicine be maintained.