

764



Medical, Ethical, and Legal Implications of Current Trends in Clinical Transplantation: An Assessment of the Respective Roles of Government and the Private Sector in the Regulation of Transplantation

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LESS THAN 20 years ago, clinical transplantation depended upon the hurried and poorly standardized harvesting of kidneys from donors whose hearts had stopped beating, and the transplantation of such kidneys into recipients on the basis of rudimentary preservation techniques. Growing acceptance of brain death as a key criterion of patient death has recently allowed procurement to become a more carefully planned component of transplantation for kidneys and extra renal organs.¹ Forty-four states have given legal sanction to the concept of brain death through formal legislation, and judicial precedent has been established in six other states.¹ The concept of brain death still generates significant anxiety and skepticism, however, in the general population,² and the success of organ procurement depends upon a clear explanation to the donor family of the scientific and clinical background for pronouncement of death on the basis of brain death. Any other course triggers suspicion by the public that this diagnosis may permit a premature termination of the patient's treatment, so as to facilitate more rapid access to retrievable organs. It has been specified that determination and pronouncement of brain death must be made by the physician involved in the initial care of the donor, in collaboration with experts in the neurosciences. This team cannot be involved in the procedure of organ donation and harvesting. Members of the transplant team are forbidden to participate in the determination of death.

The legal basis for organ donation is provided by the Uniform Anatomical Gifts Act, passed by the Congress of the United States and adopted by all 50 states since 1973.³ This act stipulates that donation is a voluntary gift

by the donor or his family, and does not include a "presumed consent" formula, which would authorize automatic organ harvesting if there is no objection by the donor's next of kin.

In spite of this legislation, and in association with the rapidly rising success rate of clinical transplantation, there has been an increasingly severe shortage of organs for transplantation. One primary factor in this dilemma is the apparent reluctance of primary care physicians to accept the failure implicit in the death of any of their patients, and a hesitancy to burden further a grief stricken family with a request for organ donation. The various religious taboos on cadaver organ donation, and the threat of malpractice suits have added further complexity to the situation.

Assessment of the situation by the Surgeon-General, USPHS, in 1983 resulted in a number of recommendations,⁴ including a systematic nationwide effort at education of physicians, nurses, and other hospital personnel, and a broad public education campaign. It was felt of importance to actively seek support from religious leaders, to encourage signing of donor cards, and for individuals to provide for organ donation by arrangement with their next of kin.⁵ Attempts have been made to

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define in unequivocal fashion the precise parameters required for diagnosis of brain death. Almost half of the States have now passed required request laws, which mandate hospitals to identify patients dying under circumstances permitting organ donation, and to approach families of such patients for authorization. Such laws contribute significantly to the protection of medical personnel from legal action, and from charges of insensitivity for asking relatives for organ donation at the time of a patient's death.

Increasing recognition of the public impact of organ transplantation stimulated the enactment by the US Congress in 1984 of a National Organ Transplantation Act, which, among other things, calls for a task force to study organ procurement and distribution, and authorizes the creation of a National Organ Sharing Network. After applying to the Office of Transplantation (OOT) of the US Department of Health and Human Services for support of such a program, an existing private non-profit corporation, the United Network For Organ Sharing, UNOS, was compelled to alter its by-laws drastically, so as to comply with contractual policy guidelines established by the OOT. After these changes, UNOS received a contract from OOT to operate a matching system for the nationwide placement of renal and extrarenal organs. UNOS was also charged with the responsibility of assuring the equitable allocation of such organs, and the collection of data on renal and extrarenal organs procured in the United States. The contract stipulates that UNOS must establish a strict priority system for placement of shared kidneys retrieved throughout the United States.

The authors share the public's awareness of the urgent needs in organ transplantation. Woefully inadequate methods of organ preservation available at this time may, however, provide a major obstacle to quick resolution of this problem. The precarious time limitations for transplantation of a still viable organ create enormous risks for patients trans-

planted on the basis of blind bureaucratic enforcement of an organ distribution and sharing system that would extend routinely beyond a given region. Also, in the allocation of live-saving organs, clinically determined local urgency of need must be given the higher priority; this primary directive of the practicing physician should take precedence over bureaucratically established nationwide requirements that fail to recognize the realities of the present situation.

Continuing growth and progress in clinical transplantation at all levels will inevitably stimulate increasing rates of organ donation throughout the United States. What is urgently needed, however, is the elaboration of standardized nationwide objective medical criteria providing for uniform allocation of organs in each region. Organs *must* be transplanted while they maintain their optimal viability. Application of such medical and scientific criteria for selection of the highest priority candidate must be delegated to individual (local) regions, because of the currently inadequate state of knowledge in organ preservation. Only those organs that cannot be used locally should be submitted to a central nationwide registry operating on the basis of the same objective criteria.

Transplantation may be damaged irreparably by adoption of rigid regulations giving preference, for example, to transplantation of a well matched but no longer viable kidney into a recipient identified on a nationwide basis, rather than to a slightly less well matched candidate for this same kidney within the local procurement region, where such a kidney would be utilized in less than 24 hours after retrieval.

The national goal of insuring an equitable allocation of procured organs is clearly in the public interest. This need may, however, be met more effectively through the nationwide adoption of standard medical criteria, to be applied within each region for the determination of priorities for transplantation. There is also serious doubt about the validity of many

of the national and state-inspired plans proposed to limit clinical transplantation to existing centers, rather than opening this opportunity to all centers that meet the basic requirements and standards. Past experience has shown that such limitations hold the dangerous potential of paralyzing rather than encouraging further progress in transplantation.

The rapid growth of clinical transplantation has stimulated growing interest in government at all levels, with an increasing emphasis upon regulation of this branch of medicine by federal and state agencies. Government can and should collaborate with the transplantation community in the development of new health policies. The emphasis, however, should be on establishing a climate of constructive collaboration, as in the setting of standards, but never on domination or control of what must narrowly remain an effort by transplant physicians and surgeons.

One of the penalties of the sensational media coverage of transplantation in recent years has been the acceptance by the general public of organ transplantation as a fully established and routine component of medical practice, ready for mass application to the treatment of disease. This critical misunderstanding of the extreme complexity of transplantation has stimulated a plethora of ambitious and probably premature organ retrieval and sharing plans—with blissful unawareness of the fact that organ preservation lags at least 20 years behind the proposed regulations. In tandem with the public clamor for more clinical transplants, there has also been a worrisome tendency by personnel other than physicians to assume responsibilities in clinical transplantation. One practice that may be particularly questionable from the medicolegal standpoint is the delegation to non-physicians of the actual tasks of excising organs for transplantation from cadaver donors. The potential hazard to the eventual recipients of such organs appears to be deserving of consideration.

One of the more unattractive features of the popularity of organ transplantation has been an ever-recurring temptation to insert political guidelines into what must remain strictly medical criteria for patient selection and treatment. Based on the argument that transplantation is supported by federal funds, and is therefore a "public service," pressure has been generated to incorporate characteristics such as national origin into the list of criteria determining a candidate's suitability for transplantation. Transplant surgeons have never inquired into the cadaver donor's nationality, creed, or color prior to removing his/her organs for transplantation. Similarly, the authors reject any but *strict objective medical criteria* for the selection of the recipients of such organs. Political decisions, or the establishment of priorities on the basis of criteria other than those developed on an objective basis by the medical community are not consistent with the high standards established by physicians for the practice of medicine.

The high visibility of organ transplantation has resulted in ever-increasing federal and state government involvement in the regulation of transplantation. This trend, no matter how well meaning, holds a very real potential of stunting the orderly growth and progress of this branch of medicine. The past twenty-five years have witnessed an exponential explosion of knowledge in this field. The life-giving potential of transplantation continues, however, to depend upon an intensive and continuing research effort. Support must be provided for a wide spectrum of studies in the laboratory and at the bedside, with painstaking avoidance of the kind of uninformed regulation that may paralyze this entire effort.

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