The Organ Allocation Controversy: How Did We Arrive Here?

Clifford H. Van Meter, MD

Chief of the Division of Cardiothoracic Surgery and Transplantation, Ochsner Clinic and Alton Ochsner Medical Foundation; Chairman of the United Network for Organ Sharing, Thoracic Organs Committee; President of the Board of the Louisiana Organ Procurement Agency

The Department of Health and Human Services (HHS) recently issued a final regulation governing the Organ Procurement and Transplantation Network (OPTN) that directs the allocation of organs to the sickest patients first without regard to a host of medical, geographic, and social factors that members of the transplant community view as an essential part of a sound organ allocation policy.

Current organ allocation mechanisms are based on policies that reflect a broad consensus of medical experts and provide equal consideration for both the needs of the sickest patients and the efficient use of organs. This system also reduces potential waste of organs by minimizing cold ischemic time, increases access to transplantation for patients in local communities, provides positive incentives for local citizens and medical professionals to support organ donation initiatives, and decreases the cost of organ transplantation.

Representatives of the American Society of Transplant Surgeons have testified before Congress that "giving priority to the sickest patients first over broad geographic areas would be wasteful and dangerous, resulting in fewer patients transplanted, increased death rates, increased retransplantation due to poor organ function, and increased overall cost of transplantation." In response, Congress enacted a 1-year moratorium on the implementation of the HHS rule and provided for a study of the current organ allocation policy and HHS regulation by The Institute of Medicine.

Introduction

Since the first successful development of kidney transplants in the mid-1950s, organ transplantation in the United States has undergone a legislative and regulatory metamorphosis (1). Until the late 1960s, organ transplantation existed without government involvement. Transplantation was predominantly a local endeavor consisting of a transplant surgeon, his or her team, and some form of organ procurement organization. Hospitals shared organs on an informal, voluntary basis (2). But as the number of organ transplants began to increase exponentially and as Medicare and Medicaid began paying for many of these procedures, the involvement of the federal government kept pace. Today we have a formal national infrastructure with governmental and quasi-governmental oversight.

On April 2, 1998, the Department of Health and Human Services (HHS) issued a final regulation governing the Organ Procurement and Transplantation Network (OPTN) and the United Network for Organ Sharing (UNOS) requiring the implementation of new organ allocation policies. The rule contains a controversial provision that directs the allocation of organs to the sickest patients without regard to geographic considerations and a host of medical and social factors that have long been viewed by members of the transplant community as an essential part of the development of sound organ allocation policy. A decade of progress toward increasing the supply of donated organs and expanding access for patients to organ transplantation is threatened by the policy. The ultimate disposition of these regulations could decide the future of organ transplantation in the United States.

Legislative History and Creation of the Organ Procurement and Transplantation Network

The legislative and regulatory foundations of organ donation and transplantation began with the enactment of the Uniform Anatomical Gift Act of 1968 (Table 1). When Congress passed the National Organ Transplant Act in 1984, it recognized that a national organ allocation system would require the careful exercise of medical judgment coupled with the voluntary support and participation of the transplant community. Thus, Congress created the OPTN, an organization outside of government, self-governed by the transplant community, and charged with the responsibility for making difficult decisions concerning allocation of a scarce and precious resource—human organs for transplantation. The Secretary of HHS was directed to contract with a private, non-profit entity to establish and guide the OPTN. UNOS was awarded the original contract and has continued to operate the OPTN since 1986.

The members of UNOS include patients; transplant recipients; donor family members; representatives of voluntary health, medical, and scientific organizations (such as the American Heart Association, National Kidney Foundation, American Medical Association, etc.); and every transplant center, organ procurement agency, and tissue typing laboratory in the United States. UNOS is governed by representatives of the transplant community, including surgeons, physicians, and professionals from organ procurement agencies, who are elected by their peers from transplant regions around the country to committees charged with developing and codifying organ allocation policy. Among their responsibilities are setting and maintaining professional standards for participation in all transplant organizations, standardizing medical criteria for listing, measuring the medical status of patients awaiting organ transplantation, and adjusting organ allocation policies to optimize benefits to potential recipients.

The dissemination of medical capability and expansion of public and professional education concerning organ donation have increased the availability of multi-organ transplant services for all Americans. Recent years have seen not only the development of techniques and technologies to foster transplant capabilities, such as lung and pancreas transplantation, split-liver transplantation, and mechanical bridges to cardiac transplantation, but also the expansion of UNOS-approved transplant centers serving patients in all regions of the country.

The Growing Need for Donor Organs

Unfortunately, the disparity between the number of patients who require organ transplantation and the number of donor organs continues to grow (Figure 1). "Since 1988, the organ transplant waiting list has quadrupled with nearly 61,000 men, women, and children waiting for a transplant today" (3). The number of organ donors, however, has grown at a much less rapid pace, providing roughly 20,000 organs for transplantation in 1997 (4). As a result, the American Society of Transplant Surgeons has stated that the primary goals of public policy should be to expand and enhance organ donation, and ensure "that the precious organs presently available provide the maximum benefit to the maximum number of Americans in an equitable fashion." (5)

Current Methods of Organ Allocation

For UNOS members, the challenges associated with the development of organ allocation policy are often described as a struggle to provide balance and equal consideration of factors related to utility and justice. The principle of utility "suggests that when the demand for transplantable organs exceeds supply, the organs should be allocated to patients who have the best chance of benefiting from a transplant. The principle of justice, which insists that the benefits and burdens of the [organ allocation] system be shared among all patients equitably, would favor the patient who had the most urgent need or has waited the longest" for a transplant (4).

Organ allocation policies must also be crafted to reflect specific medical factors, such as the limited viability of donor organs in the absence of oxygenated blood. Maximum cold ischemic times vary by the type of organ. Hearts must be transplanted within approximately 4 hours and livers retain viability for approximately 12 hours, with maximum cold ischemic time influenced by the condition of the donor organ.

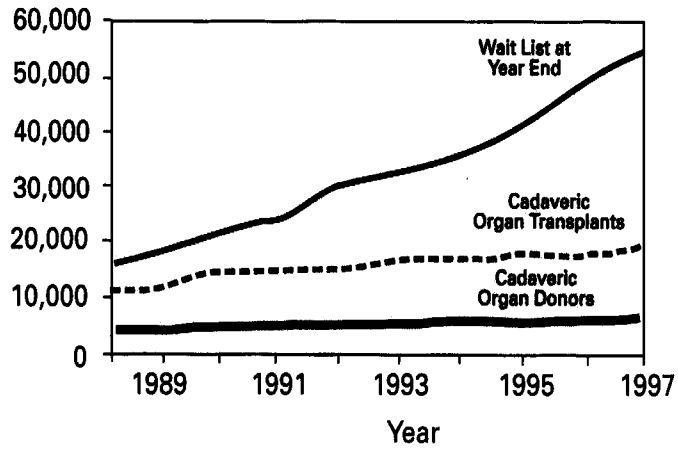

Figure 1. Comparison of donors versus number of waiting patients (4).

Table 1. Chronology of Legislation and Regulation

- **Uniform Anatomical Gift Act (1968)**
  Established a legal foundation for organ procurement and donation, recognizing the right of an individual or family member to donate organs.

- **End Stage Renal Disease Program (1972)**
  Congressional amendment to Medicare program to include renal dialysis and transplantation, establishing financial responsibility only.

- **National Organ Transplant Act (NOTA) (1984)**
  Called for the creation of a task force to study transplant issues and provided grants for organ procurement organizations (OPOs), in effect establishing an Organ Procurement and Transplant Network (OPTN). This act enabled the Department of Health and Human Services (HHS) to contract with a private nonprofit system for matching organs and individuals.

- **Award of Federal Transplant Contract to United Network for Organ Sharing (UNOS) (1986)**

- **Omnibus Budget Reconciliation Act (1986)**
  Federal government imposed regulatory standards on transplant hospitals as a requirement for participation in Medicare and Medicaid Programs. Hospitals and OPOs were required to become members of the UNOS in order to receive Medicare and Medicaid reimbursement for transplant procedures.

- **Amendment to NOTA (1988)**
  The amendment reaffirmed that "the OPTN should resolve any issues regarding the fair and effective distribution of organs. Patient welfare must be the paramount consideration."

- **1989 Notice in the Federal Register**
  Provided that OPTN rules cannot take effect unless approved by the Secretary of HHS (never enforced and subject to multiple interpretations).

- **Amendment to NOTA (1990)**
  Directed OPTN to "assist OPOs in the nationwide distribution of organs equitably among transplant patients" and refined service areas of OPOs.

- **1991 Notice in the Federal Register**
  Provided Medicare coverage for certain liver transplants.

- **1994 Notice by HHS**
  Secretary issued rules for listing candidates on a nationwide computer network and for allocating organs. The rules "provide for Federal oversight of the processes by which the OPTN allocates organs" but recognize that "OPTN has responsibility for developing policies governing organ transplantation."

- **1998 Final Rule by HHS**
  Directs OPTN to establish (1) minimal listing criteria to be used by all transplant centers; (2) status categories to be based on objective medical criteria; and (3) policies to allocate organs among transplant candidates in order of decreasing medical urgency status, with waiting time in status used to break ties within status groups. Neither place of residence nor place of listing shall be a major determinant of access to a transplant.

Increases in cold ischemic time raise the probability that an organ will not function after transplantation. In addition, allocation policies should weigh the fact that the most severely ill patients awaiting transplantation have lower survival rates and an increased need for a second organ transplant when compared with the entire population of transplant patients. Finally, certain patient groups require special medical consideration, including children and patients with highly sensitized immune systems.

UNOS has addressed this situation through development of an organ allocation policy based on a broad consensus of experts in the transplant community, striking a balance between the many competing objectives surrounding the concepts of justice and utility. Organs are first allocated to patients within the boundaries of the local organ procurement organization (OPO) (which in Louisiana encompasses the entire state), then to patients in the contiguous region, then to patients nationally. Organs are offered first to the sickest patients in a local OPO area, then to patients in the same area with less medically urgent conditions if a patient with an urgent medical need is not available. If there are no suitable patients in a local OPO community, this same allocation process is replicated at the regional and then national level. (Note: There is a different allocation system for kidneys that addresses special problems involving the medical compatibility of patients and donor organs.) Within each status group, patient priority is determined on the basis of numerous factors, including blood type and time on the waiting list.

This system provides equal consideration for both the needs of the sickest patients (Justice) and the efficient use of organs (Utility) "by permitting transplantation of some less urgent patients who have a higher probability of surviving the longest and not needing a second transplant (further depleting the already scarce resource)." (6) A balanced approach to organ allocation results in high overall survival rates, and also distributes "the benefits and burdens of organ transplantation among patients throughout the country with the most urgent" and severe medical conditions (4). This allocation mechanism also reduces potential waste of donated organs by minimizing cold ischemic time; increases access to transplantation for patients in local communities, many of whom are from minority and economically disadvantaged populations; provides positive incentives for local citizens and medical professionals to support organ donation initiatives; and decreases the costs of organ transplantation attributable to medical complications, the need for hospital care, and transportation and procurement costs.

The HHS Final Rule

The HHS regulation contains a sweeping organ allocation policy that overrides the established OPTN system and replaces it with a mechanism that allocates organs to the sickest patients first without regard to geographic location. More specifically, the HHS rule creates a policy "to allocate organs among transplant candidates in order of decreasing medical urgency status, with waiting time in status used to break ties within status groups. Neither place of residence nor place of listing shall be a major determinant of access to a transplant" (7). Patients who need liver transplants will be the first individuals affected by the new policy.

The main justification for the policy is an inaccurate assertion that the sickest patients are treated unfairly by the current allocation system and suffer from wide disparities in waiting times (8). HHS officials claim that the rule will equalize waiting times, thus creating a fairer allocation system. The final rule also acknowledges, however, that "current measures of waiting time disparities are weak because the lack of listing standards does not create uniform, status-related measures..." (9). Further, the regulation concedes that these policies will lead to lower survival rates, fewer patients transplanted, and longer time on the waiting list for most patients (10). The final rule also states that "the Secretary has final authority over OPTN policies and procedures" (11) and that, "If the Secretary objects to a policy, the OPTN may be directed to revise the policy consistent with the Secretary's direction." (12)

Public Comments and Analysis of the HHS Rule

The new regulation has been met with widespread dismay and opposition by members of the transplant community. One major point of contention involves whether the regulation creates a new organ allocation system. Officials of HHS describe the regulation as establishing broad "performance goals" to be achieved through policies developed by the OPTN. Representatives of UNOS have stated that the "policies, as expressed in this regulation include specific elements of what we interpreted as a required new organ allocation policy–including the exact criteria by which organs are to be allocated. Relieved of the allocation policy-making duties, the OPTN's remaining task... is that of developing detailed procedures for implementing the Secretary's policy." (13)

The specific directives of the regulation have also generated enormous concern because the policy is medically unbalanced. "When asked during a national conference call... whether the new policy would yield the greatest benefit for the greatest number of patients," HHS officials "admitted that the new rule favors equity over utility" (14). In response,

Dr. Ronald Busuttil, President-elect of the American Society of Transplant Surgeons and Chief of the Division of Liver and Pancreas Transplantation at the University of California at Los Angeles School of Medicine, testified before Congress that "giving priority to sickest first over broad geographic areas would be wasteful and dangerous, resulting in fewer patients transplanted, increased death rates, increased retransplantation due to poor organ function, and increased overall cost of transplantation." He also stated that "the rationale for rushing this rule into effect may largely have disappeared." Since the implementation by UNOS of standardized medical criteria for listing an the medical status of patients, "data for 1998 through the month of August" indicate "that for status-one patients, the most critically ill, the mean waiting time for a {liver}transplant– across the country – now is running 4 days, with not a great deal of regional variation" (15).

In addition, UNOS and many observers have expressed great concern that implementation of the HHS rule would result in the allocation of organs to a small group of large transplant centers, reducing access to transplantation for patients in local communities, particularly for Medicaid and economically disadvantaged recipients who cannot afford to seek their care at medical centers in distant locations. This policy would also undermine local communities that have been particularly successful in their efforts to stimulate organ donation, failing to account for the linkage between increased organ donation and decreased patient waiting times within OPO service areas. On a broader level, the rule does not assess the wide disparities in OPO performance and how these variations influence patient waiting times in specific regions of the country.

Transplant surgeons fear that new surgical techniques, such as the split liver procedure, where 1 organ is divided and used to serve 2 patients, would be impaired by the regulation because the success of the procedure is dependent upon minimizing cold ischemic time. "Full utilization of this split-liver procedure would potentially increase available donor livers by close to 1,000 per year in the U.S." (15).

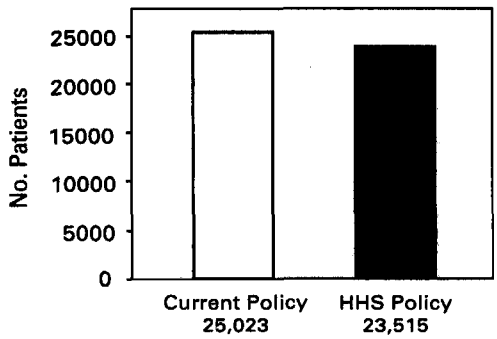

Figure 2. Comparison of liver allocation policies: patients transplanted 1997-2003. Approximately 4,000 transplants are done each year (4).

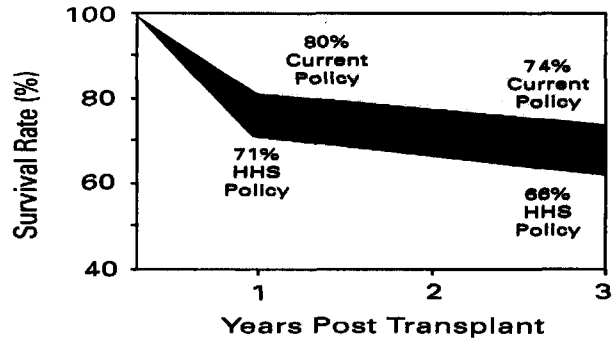

Figure 3. Comparison of liver allocation policies: patients survival rates (4).

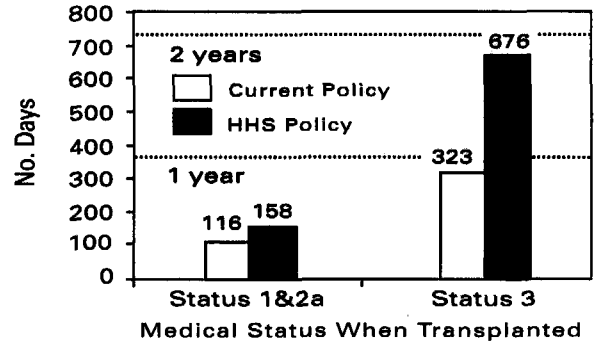

Figure 4. Comparison of liver allocation policies: projected waiting time for liver transplants (4).

From a quantitative perspective, "data generated by a national panel of experts" (16), led by Alan Pritsker, PhD and UNOS staff scientists, "predict the following:...over a seven-year period, 1,508 fewer patients {will] be transplanted" (4, 16) (Figure 2), the survival rate for the entire patient population will fall by 9.3% (Figure 3) (4), and patients will have to wait much longer for a transplant (Figure 4) (4), with many individuals throughout the country experiencing a substantial increase in waiting time for a liver transplant of between 51 and 86 days (Figure 5) (17). "Further, the model did not assume any increased organ wastage despite the fact that" (13) the median distance for transportation of donor organs to recipients will increase from 71 miles to 930

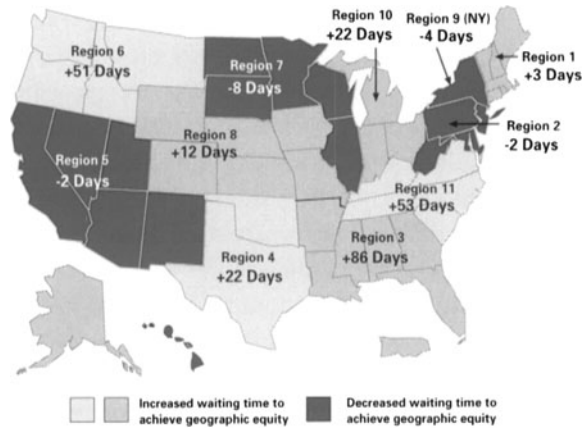

Figure 5. Projected change in patient waiting times for liver transplantation under HHS policy.

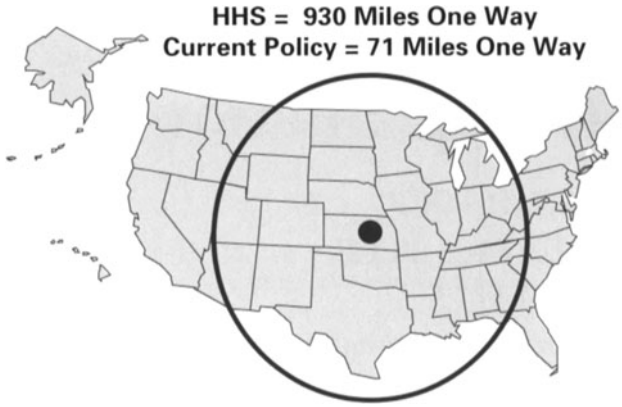

Figure 6. Comparison of liver allocation policies: transportation of organs and doctors, median miles per transplant.

miles (Figure 6) (4). The regulation also suggests that the percentage of organs donated and provided to patients in local OPO areas may drop from approximately 80% to 20% (18), "a fact that could be tremendously damaging to local organ donation efforts" (16).

Legislative and Legal Responses

In response to the HHS rule, Congress intervened in the regulatory process by enacting legislation to extend the effective date of the regulation from July 1, 1998 to October 1, 1998, and conducted hearings to review the impact of the HHS policy. Both the American Society of Transplant Surgeons and UNOS called on members of Congress to block the implementation of the HHS rule in hearings held on September 10, 1998. The President-elect of the American Society of Transplant Surgeons testified that, "the Department in subsequent discussions with our society has told us that in fact, giving priority to sickest patients first– in effect, creating a national waiting list– is not the intent of the rule. Nevertheless, they [HHS] have not changed the rule to make it clear that it would not require transporting organs across broad geographic regions." The regulation "as it now stands, would harm a system which we have tried to make as fair as humanly possible" and "permit substitution of the Secretary's judgment on organ allocation for the judgment of medical professionals. We do not believe this is what was intended by Congress when it enacted the National Organ Transplant Act" (15).

In late September, the State of Louisiana, led by Attorney General Richard Ieyoub, the Louisiana Organ Procurement Agency, and Louisiana transplant centers, filed a lawsuit in a Baton Rouge Federal Court challenging the new HHS organ allocation scheme. Judge Ralph Tyson issued a stay order enjoining HHS from enforcing the final rule until the legal challenge is resolved.

Finally, as part of the broad agreement on the federal budget crafted in October of 1998, members of Congress, lead by Representative Bob Livingston, and officials of the Clinton Administration agreed to a 1-year moratorium on the implementation of the HHS rule. The legislation also provides for a study of the current organ allocation policies and the HHS regulation, to be conducted by The Institute of Medicine, and mechanisms for future discussions between UNOS and HHS officials (19).

Conclusions

The organ allocation controversy will be addressed in the coming year by the Institute of Medicine, representatives of HHS and the transplant community, members of Congress, and, perhaps, the Federal Courts. In the end, we must hope for three positive developments: first, that the public never be concerned or led to believe that organ allocation policy is anything less than the best that can be achieved; second, that organ allocation policy remains in the hands of the transplant medical community under the appropriate oversight of federal agencies; finally, that the full focus and effort of all parties be redirected toward the goal of enhanced public and professional education leading to increased organ donation.

References

1 Murray JE, Merrill JP, Harrison JH. Kidney transplantation between seven pairs of identical twins. Ann Surg 1958;148:343.
2 Prottas J. The Most Useful Gift: Altruism and the Public Policy of Organ Transplants, San Francisco: Jossey, Bass,1994.
3 Testimony of Dr. William W. Pfaff before the Senate Appropriations Committee, Labor, Health and Human Service, Education Subcommittee, September 10, 1998, page 1.
4 United Network for Organ Sharing. Congressional Staff Briefing: Impact of HHS OPTN Regulations. May 1, 1998.
5 American Society of Transplant Surgeons: Position paper on the Department of Health and Human Services Rule on the Organ Procurement and Transplantation Network, June 1, 1998, p. 1.
6 United Network for Organ Sharing. The UNOS Statement of Principles and Objectives of Equitable Organ Allocation. June 29, 1994, p. 165.
7 Federal Register. Rules and Regulations. April 2, 1998;63(63):16335.
8 Federal Register. Rules and Regulations. April 2, 1998;63(63):16298.
9 Federal Register. Rules and Regulations. April 2, 1998;63(63):16327.
10 Federal Register. Rules and Regulations. April 2, 1998;63(63):16325.
11 Federal Register. Rules and Regulations. April 2, 1998;63(63):16299.
12 Federal Register. Rules and Regulations. April 2, 1998;63(63):16334.
13 www.unos.org. Response to HHS Concerns about UNOS Statements Regarding the Regulations. May 1998.
14 The Patient Access Coalition. Comments on the Department of Health and Human Services' April 2, 1998 Final Rule Regarding the Organ Procurement and Transplantation Network, August 28, 1998.
15 Statement of Ronald W. Busuttil, MD, Ph.D., FACS, before the hearing of the Subcommittee on Labor, Health and Human Services and Education of the Senate Appropriations Committee, September 10, 1998.
16 Sollinger H, MD. Transplants: Who should get them first; how to raise donation rates. June 18, 1998;Wisconsin State Journal, page 1.
17 Federal Register. Rules and Regulations. April 2, 1998;63(63):16327.
18 Federal Register. Rules and Regulations. April 2, 1998;63(63):16324
19 Conference Report 105-825 to accompany H.R. 4328. "Making Omnibus Consolidated and Emergency Supplemental Appropriations for Fiscal Year 1999".