

RECOMMENDATIONS TO THE DEPARTMENT OF HEALTH
AND HUMAN SERVICES
REGARDING

THE ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

I. ALLOCATION OF LIVERS FOR TRANSPLANTATION:

National Transplant Action Committee (NTAC) believes that every patient on the waiting list for a liver transplant should have a fair opportunity to find a donor and receive a transplant. The waiting times for medically similar patients should be the same. This can be achieved by eliminating the arbitrary local OPO boundaries and allocating organs on a wider basis.

NTAC is keenly sensitive of how important local access to organ transplants can be. Many of us went through our transplant experiences at a time when there were fewer liver transplant centers. And, the distance that individuals had to travel to find a hospital performing liver transplants was much farther than today.

NTAC has analyzed the UNOS ULAM modelling data to determine what impact wider sharing would have on local access. We compared the current allocation system with the various other allocation options modelled by UNOS. We believe that greater sharing, based upon medical necessity, will have a minimal impact on local access. Assuming that any center unable to perform more than 10 transplants per year would close, we found that approximately 12 centers would fall below an annual volume of 10 liver transplants per year and become vulnerable. However, of these, only two centers performed more than 10 transplants in 1995. The 12 centers were in larger metropolitan areas with at least one other transplant center within reasonable travel distance. If these 12 centers closed, another center would be nearby and patients would continue to have easy access to a local transplant center.

NTAC has also examined the geographic location of all centers that performed fewer than 20 transplants in 1995. Once again, we found that 80% of those centers are in large metropolitan areas with at least one other liver transplant center near by. Another seven of the smaller centers are within a three to four hour driving time of a larger liver transplant center.

NTAC finds that wider sharing of livers in liver transplantation will equalize waiting times while not having any significant impact on local access to liver transplantation. Our findings ensure that low income and Medicaid covered patients would continue to have the same access to transplantation as is usually the case.

We support an outcome-based public policy in liver transplantation. The HHS allocation rules should embrace a public policy that will foster equity among patients waiting for transplants while still enabling the medical community the flexibility to adapt medical criteria to changing technology. Therefore we propose that HHS adopt the following principles:

The OPTN contractor shall maintain a system of allocating organs for liver transplantation that:

a. prioritizes patients on the national waiting list based upon medical necessity,

b. utilizes geographic regions large enough to ensure that the waiting times for all individuals on the national waiting list within the same medical status are approximately the same, and,

c. ensures that patients listed in a higher priority status are offered a donated organ before patients of a lower priority.

Currently, the process of prioritizing patients on the national waiting list is loosely based upon whether the patient is in the ICU, is an in-patient at a transplant facility, is homebound and under care, or is still functional either at school or work. We believe that medical criteria for each status should be established based more upon measureable clinical indicators and conditions.

In addition, the current OPTN contractor, UNOS, has recently implemented a policy change that gives highest priority for liver transplants to patients with limited, mostly acute, conditions and reduces the highest priority previously given to patients with chronic conditions. UNOS claims to have promulgated this rule change based upon the belief that patients with acute conditions have a lower post-transplant mortality rate than those patients with chronic conditions.

According to data recently published in the 1996 UNOS Annual Report, patients transplanted because of acute liver conditions actually have a higher post-transplant mortality rate than patients with chronic conditions. The one year and three year survival rates for patients with acute liver failure are 70.8% and 67.6% respectively.

The same rates for all patients are 80.0% and 73.6%. Even if one assumes that all acute liver failure patients were Status 1 when transplanted, the same rates for all status 1 patients are 69.9% and 64.1%. Clearly, the scientific data do not support the UNOS policy decision.

Instead, NTAC believes that the recent UNOS rule changes were based upon distrust among transplant centers and the manner in which individuals are prioritized for liver transplants. Patients with acute liver failure are very clearly identifiable and there is little question about their medical urgency. We propose that HHS adopt the following regulation with respect to these issues:

The OPTN contractor will develop clearly defined medical criteria for prioritizing patients in each status on the national waiting list for liver transplants. Such criteria shall:

- a. provide that the most medically appropriate individuals with the greatest medical need for a liver transplant be given the highest priority on the waiting list, and,*
- b. be based upon sound verifiable medical and scientific principles.*

The OPTN contractor shall establish a system of monitoring transplant center compliance with the patient listing and prioritization standards, either through regional review boards or through a single national review board. Any violations of the established rules shall be reported to the Secretary.

Finally, with respect to liver allocation, NTAC is concerned that the use of total waiting time on the transplant list, as a means of selecting patients for transplant, may encourage premature listing on the waiting list and result in a larger waiting list than is actually necessary. Therefore we suggest:

In so far as the use of total cumulative waiting list time, as a means of prioritizing patients for liver transplants, may result in the premature transplantation of patients with chronic liver disease and may artificially inflate the transplant waiting list, waiting time in each medical priority status shall be calculated separately and only waiting time in the patient's current

medical priority status shall be considered when selecting patients for organ transplants from those individuals on the waiting list.

II. OVERSIGHT AND OPERATION OF THE OPTN:

NTAC is very concerned about the organization of the OPTN and the role that the public, through qualified transplant recipients and patient advocates, has in the operation, organization, and rule making of the OPTN. The OPTN contractor's board of directors and its rule making process are dominated by the transplant centers. There are over 250 transplant center members and fewer than 12 general public members of UNOS.

In recent years, UNOS has increased the number of transplant recipients on the board of directors. However, the process by which these individuals are selected for the board is still dominated by transplant centers. As such, the patients and members of the general public who are selected for service on UNOS committees and the UNOS board are carefully screened and the patients' message filtered. Although the number of recipients, family members and donor family members on the UNOS board has increased, transplant centers control the debate and the votes and the public policy positions of the leading transplant patient advocates and organizations continue to be ignored.

The recent hearings on liver allocation conducted by HHS in Bethesda, MD., offers a clear example of the problem. Representatives from NTAC, Transplant Recipients International Organization (TRIO), the American Liver Foundation, as well as many patients and recipients from around the country, were unanimous in their support of HHS and its rule making authority on this matter. However, UNOS responded by claiming overwhelming support for its positions at the hearing. In a letter to the UNOS board of directors, UNOS president James Burdick criticized the patients who testified against UNOS as "profoundly ignorant" about the matters in this debate. The fact is that many of those who spoke on behalf of changing the system have followed this debate closely since its beginning and have studied the UNOS data very thoroughly. Their problem is not ignorance. Instead, it's the fact that they understand the situation all too well that has earned them the contempt of the UNOS president.

Not only is there a real lack of representation of patient interests on the UNOS board, there is also a disproportionate level of representation among the transplant centers themselves. Centers that perform 10 transplants per year have as much input into UNOS policy as those centers performing 200-300 transplants per year. Those centers performing a greater number of transplants represent more patients, more transplant professionals, and a greater stake in our public policy on organ transplantation.

NTAC also has concerns about whether the OPTN contractor should be in a position to promulgate public policy in organ transplantation when its members and board of directors have such a personal financial interest in the outcome of any such policy decisions. We believe that the public policy decisions should be made independent of special interests.

There is nothing expressed or implied in the National Organ Transplant Act that requires the OPTN and the OPTN contractor be one and the same. The U.S. Senate concurred on this point during its deliberations on the National Organ Transplant Act in 1996: "The Network was described in the original law as a 'private entity.' The committee views the original designation as a 'private entity' to represent an independent voluntary organization which would function outside of a government agency, with government oversight, and would represent the interests of the public and the transplant community. The committee believes that the original designation was not a legislative mandate that the Network should become a subsidiary of, and therefore synonymous with, the Network contractor." (U.S. Senate report 104-256, April 22, 1996.)

Therefore, NTAC proposes that the Secretary establish a *National Organ Transplant Oversight and Advisory Committee* as follows:

The Committee should include representatives from transplant professionals, other health care professionals, civic and public leaders, and the public at large.

I. Representatives of transplant professionals would be selected by the Secretary from the various specialties in transplantation and include representatives of organ procurement organizations and histocompatibility labs.

II. Health care professionals would be selected by the Secretary and could not be employed by the Network contractor, a transplant center, an OPO, or a histocompatibility lab.

III. All other public members would be selected by the Secretary and could not be directly employed by a transplant center, an OPO, or a histocompatibility lab.

a. The Secretary would solicit recommendations from transplant advocacy organizations in the selection of public members and give priority to transplant recipients and family members of transplant recipients and donor families.

IV. All rules and regulations, as well as amendments to existing rules and regulations, promulgated by the OPTN contractor and directly related to the operation of the OPTN, would be subject to review and approval of the Committee and the Secretary.

a. Any proposed changes would be forwarded immediately to the Committee upon approval by the OPTN board.

b. Within 60 days the Committee would submit its report and recommendations to the Secretary on any proposed rules changes. During this 60 day period, the Committee may request from the OPTN, and the OPTN shall provide, data and information to support and explain the changes. The Committee may receive and consider data and information from other sources as well.

c. Within 30 days after receipt from the Committee, the Secretary would publish the proposed changes as approved or modified by the Committee for public comment and proceed to finalize the rule as required in the Administrative Procedures Act.

d. Upon showing good cause, the OPTN board may request immediate implementation of a proposed rule. The Committee may approve the implementation of an interim rule that would be in effect until the proposed rule is adopted, amended, or rejected by the Secretary.

V. The Committee, at its discretion, may propose changes to the OPTN rules and regulations and submit those proposals to the Secretary for review and approval.

THE IMPACT OF GREATER ORGAN SHARING
ON THE AVAILABILITY OF LIVER TRANSPLANTS
AT THE "LOCAL" LEVEL

PREPARED BY
NATIONAL TRANSPLANT ACTION COMMITTEE

INTRODUCTION:

There has been a great deal of speculation about the impact that a system of greater organ sharing might have on the availability of local transplant centers in the field of liver transplantation. The current system of organ allocation gives priority to all local patients on the waiting list before a donated organ is made available to any other patients on the national waiting list. Patient advocates have been calling for a system that would direct livers to the most medically needy patients through a system of wider sharing of organs across local and regional boundaries.

Those opposed to "medical needs based sharing" have argued that such a system will benefit a few large transplant centers and result in the closure of many other small to medium liver transplant centers.

We believe that this is the first analysis to date that attempts to determine the impact that greater organ sharing would have on access to transplantation. We have analyzed data developed by the United Network for Organ Sharing (UNOS) and have concluded that an allocation system based upon medical need would not have a detrimental impact on a patient's ability to gain access to a nearby liver transplant center. We compared the current system with one that is needs based. The alternative system would allocate livers to all patients on the national waiting list with the same medical urgency before patients with a lower medical priority.

We have concluded that under such a system only about 12 liver transplant centers would be at risk of closing because of a lack of volume. Most of the country's 101 transplant centers would see little change in their overall status. In fact, greater sharing would result in fewer low volume transplant centers and an increase in medium to large transplant centers. Given the impact that volume and experience have on patient survival, we conclude that changing the current system will also have a positive impact on the quality of care available in our nation's liver transplant centers.

METHODOLOGY

Our analysis is based upon information developed and published by UNOS. UNOS created the UNOS Liver Allocation Model (ULAM) as a tool to evaluate the impact that changes with liver allocation would have on the system. ULAM computer reports include a variety of outcome measurements including the number of livers imported or exported for any given region. By comparing the results of different allocation algorithms we can determine any net increase or decrease in the livers available for transplantation in each of the UNOS regions. We have used the ULAM data in conjunction with the UNOS Report of Transplants by Center 1988-1995.

We grouped the transplant centers to determine the total transplants performed in each region in 1995 and then adjusted the total depending upon the change in the exports/imports according to the ULAM data. We then prorated the difference equally across all the transplant centers in the region.

This analysis could be enhanced by determining the export/import rate

for each local OPO service area. However, we feel that this method of analysis still provides an accurate appraisal of the impact that greater sharing would have on liver transplantation.

In our examination of the data we compared the current system to one that allocates livers according to medical priority (all status 1 patients locally, regionally, and nationally before transplanting patients with a lower medical status). These different systems are modelled as policy number 95 (current policy) and policy 97 (proposed) and were included in the Report of the UNOS Liver and Intestine Committee for the November 1996 UNOS board meeting.

RESULTS

We assumed that a transplant center would close if the following conditions existed: 1. the volume of the center decreased to the point where it performed fewer than 10 liver transplants per year, and 2. it was not associated with a larger transplant program (*ie.* a children's hospital paired with a larger transplant program). We found that 12 liver transplant programs would be in jeopardy of closing because of a lack of volume. However, ten of those centers already performed fewer than 10 liver transplants in 1995 while the two others only performed 10-24 transplants.

The mix of small, medium, and larger transplant centers would remain relatively similar between the two systems. The number of centers performing fewer than 10 transplants per year would decrease by 50%. There would be virtually no change in the composition of the remaining transplant centers. However, the proportion of transplant centers performing more than 25 transplants per year would increase from 54% of

all centers to 60%.

Finally, there would not be a dramatic increase in the number of transplants performed in the country's largest transplant centers (centers performing more than 100 transplants annually). In 1995, the largest centers performed 1218 transplants and accounted for 31.1% of all liver transplants. Under a medically based system those centers would perform 33.0% of all transplants for a total of 1293.

CONCLUSIONS

Claims that a needs based allocation system based upon wider sharing of organs would adversely impact access to transplant programs are unfounded based upon the UNOS data. Using our criteria, we find that 89 of the 101 hospitals performing liver transplants in 1995 would continue to remain viable and provide service to a broad cross-section of the country. Of the 12 centers in jeopardy of closing, only 2 of those centers performed more than 10 liver transplants in 1995. In total, the 12 at risk transplant centers performed a total of 65 liver transplants in 1995, accounting for 1.7% of the total for the country as a whole.

Geographically, the 12 centers serve patients in 10 locations. Of these, six of the locations are in large metropolitan areas that include at least one, larger, liver transplant center. Two of the other locations are within two hours driving time of another transplant center and one other is within three hours driving time of a larger center. The final location is more remote and is approximately four to five hours driving time from the nearest transplant centers.

The ULAM data has shown that a medically based allocation system is much more equitable than the current system. The proposed system used

in our analysis showed the lowest regional standard deviation in the ratio of liver transplants to patients on the waiting list. Liver transplant patients could also benefit from a higher quality of care that a needs based system might provide. A relationship has shown to exist between transplant center volume and patient survival. In 1995, 54% of the nation's transplant centers performed 25 or more procedures. Under the medically based sharing system that percentage would increase to 60%.

The development of the nation's liver transplant system has been an ad-hoc process. Hospitals have been able to open and operate liver transplant centers by simply meeting the professional medical and staffing requirements of UNOS. There has been no needs based planning. As a result, we have 2 transplant centers in a city of 200,000 that served only 16 patients in 1995. In a city of 500,000 individuals, 3 transplant centers performed a combined total of only 31 transplants. In another region of the country, a hospital is attempting to begin a liver transplant program despite the fact that, less than 1 hour away, 4 transplant centers perform a combined total of about 100 liver transplants per year. Clearly, very little thought or planning has gone into our transplant system.

A system that allocates organs based upon medical necessity helps correct this problem. A needs based system ensures that the most medically deserving patients are given the highest priority when a donated liver is found. By controlling the flow of resources in this manner we can overcome the ad-hoc system that has developed throughout the past decade and move closer to a system that meets the health care demands of the American public. Changing the liver allocation system will not have the adverse impact on "local access" that many have claimed. Instead, needs based allocation will steer resources in the direction of those regions, and those patients, where the nation's health care system can derive the greatest benefit.

TABLE 1

VOLUME UNDER PROPOSED SYSTEM

	0-9	10-24	25-49	50-99	100+
1995 VOLUME					
0-9	11	1			
10-24		19	3		
25-49		5	21	4	
50-99			6	12	1
100+					6

The left hand column represents the categories of liver transplant centers based upon 1995 volume. The top row shows the impact of the proposed allocation system. For example, of the centers performing 25-49 transplants in 1995, 5 would perform 10-24 transplants under the proposed system, 4 would perform 50-99 transplants, and 21 would remain in the same category.

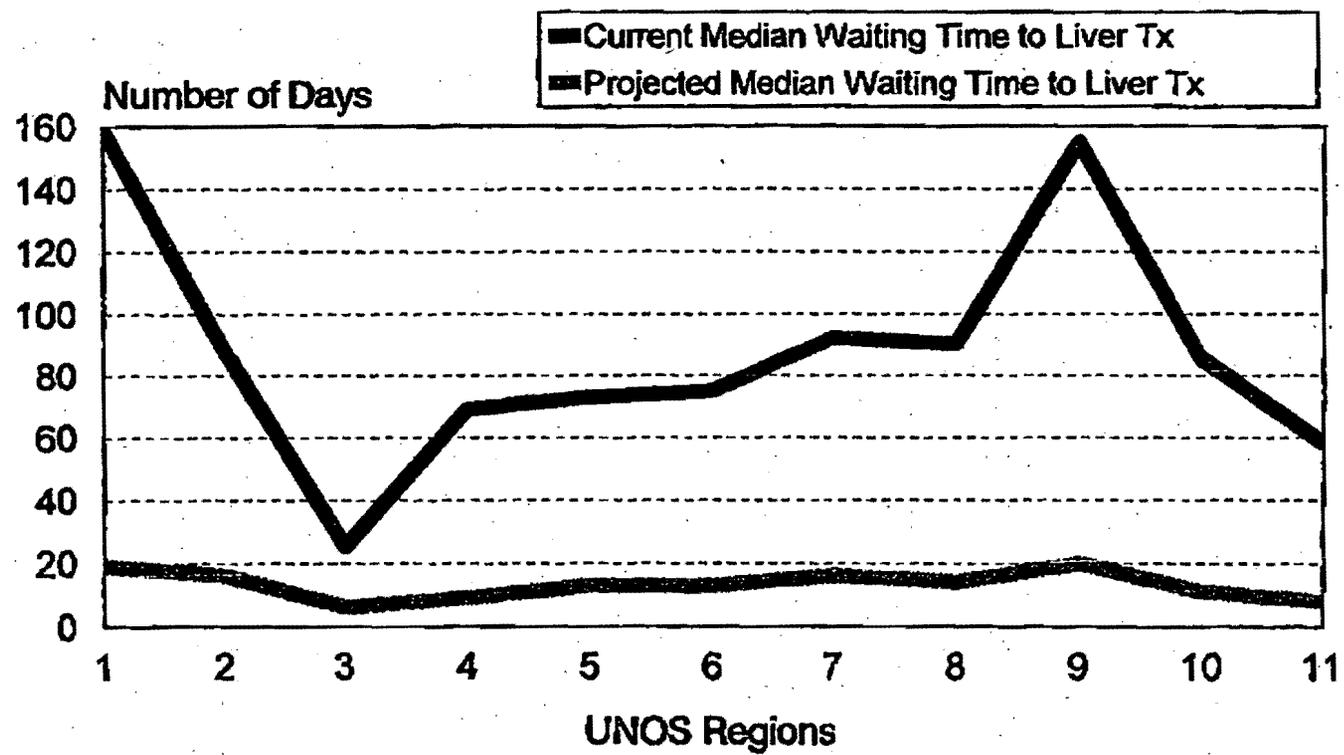
TABLE 2

LIVER TRANSPLANT CENTERS CATEGORIZED

BY VOLUME

	CURRENT SYSTEM	NEEDS BASED
0-9	22	11
10-24	24	25
25-49	30	30
50-99	19	16
100+	6	7
TOTAL	101	89

Regional Waiting Time Comparison



1992-94 Actual results vs. ULAVI projections based on liver recovery rates at all OPOs being equal to the top OPO. Recovery rate for 1995: 30 donors per million and 80% liver recovery.

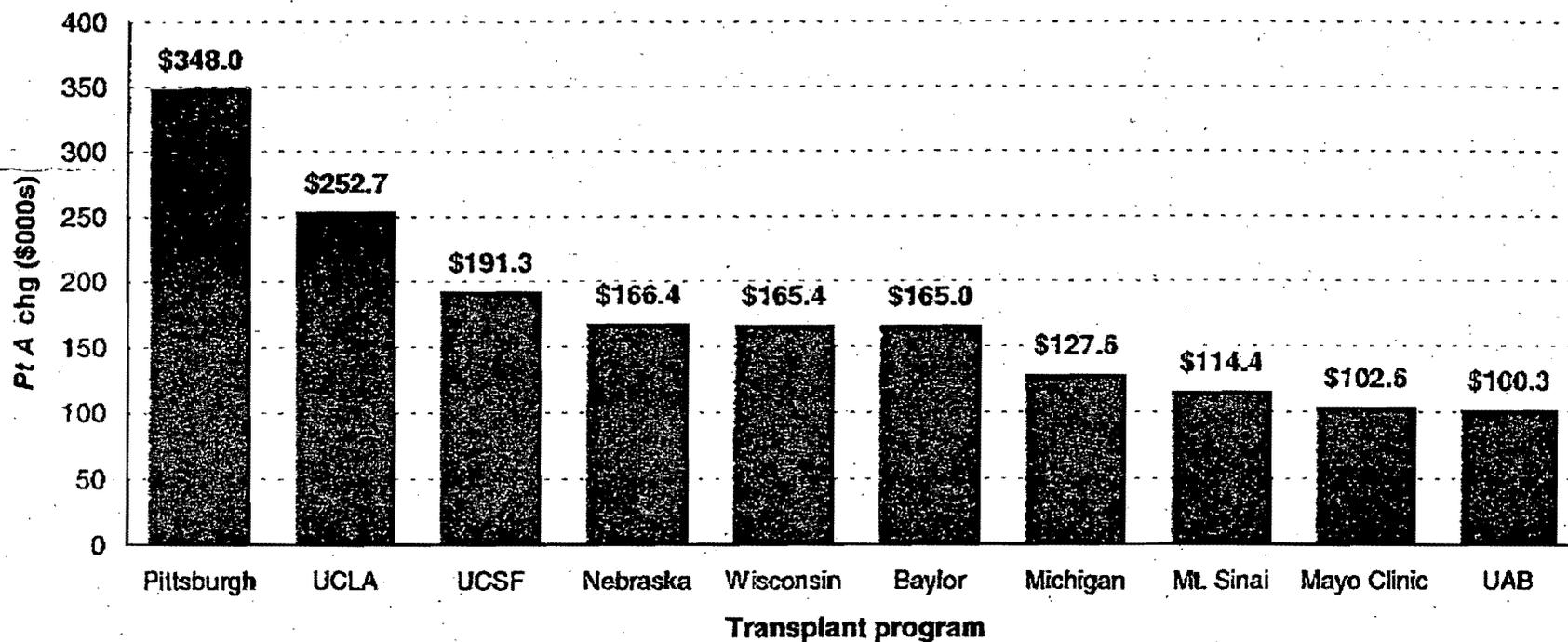


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12/04/96 WED 09:44 FAX 606 581 3174

Mean Actual Part A Charge (\$000s) for Entire Stay in 1995

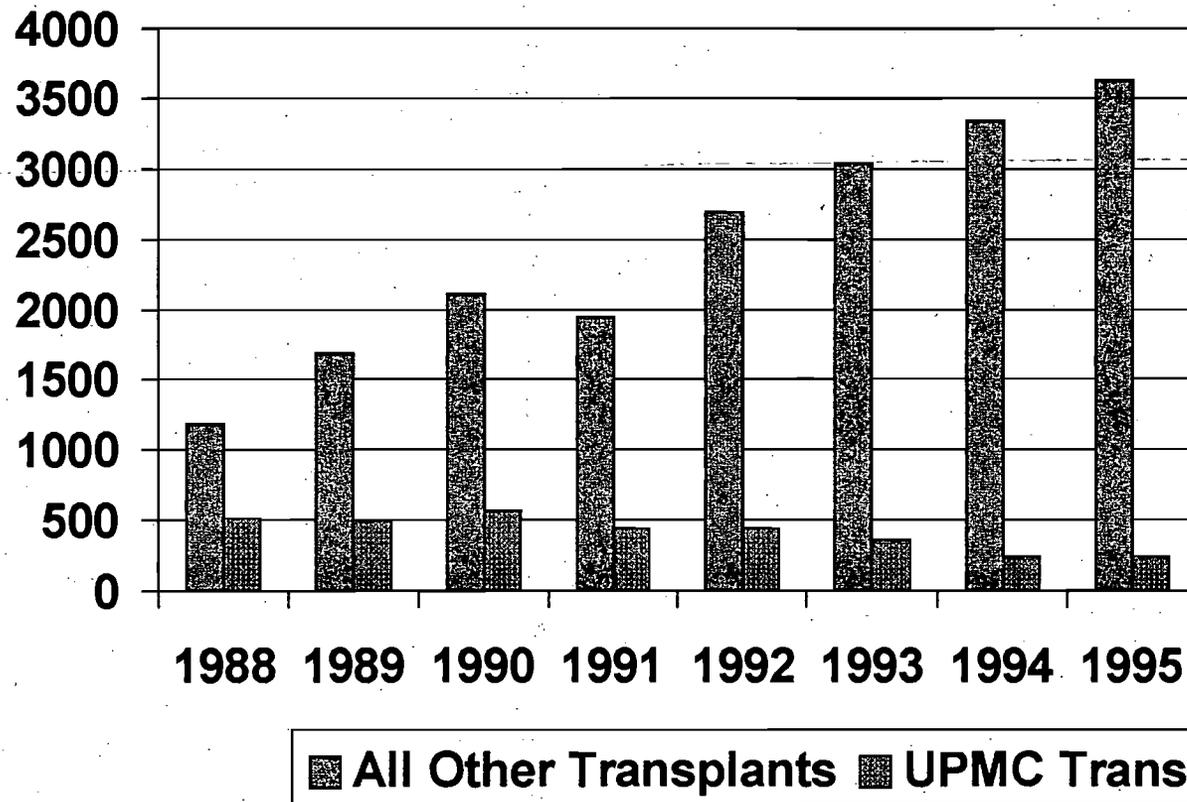
Liver Transplantation at Major Programs in United States



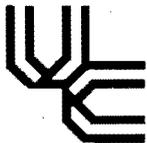
SOURCE: R. W. Evans, Ph.D., Section of Health Services Evaluation, Mayo Clinic, Rochester, MN.



Liver Transplants Performed 1988-1995



University of Cincinnati
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Douglas W. Hanto, M.D., Ph.D.
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File: ~~transplants~~ Liver Transplant
(File w/ rest of organ
stuff I gave you yesterday)

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December 2, 1996

The Honorable Donna Shalala
Secretary of Health and Human Services
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Dear Madame Secretary:

We are concerned about recent actions taken by your office that are outlined in a letter from Philip R. Lee, M.D., Assistant Secretary for Health, to James F. Burdick, M.D., President of the United Network for Organ Sharing (UNOS) dated November 8, 1996. These actions appear to have been taken, at least in part, because of your concern with the specific recommendations regarding liver allocation policy made by the Liver and Intestinal Organ Transplantation Committee to the UNOS Board of Directors that were unanimously approved by the Board. In addition there appears to be a perception that the discussions and decisions concerning liver allocation has lead to what Dr. Lee has termed "... considerable unresolved controversy within the transplant community." We would like to offer our perspective on the recent decisions concerning liver allocation and your response to these decisions. We represent 74 of the 119 registered liver transplant programs in the United States (62%). Our programs performed 2,316 liver transplants in 1995 out of a total of 3,846 (60%).

We would like to emphasize that over the past three years liver allocation has been studied extensively using the UNOS Liver Allocation Model (ULAM). This computer modeling allows the assessment of the impact alternative liver distribution and allocation policies have on several performance measures that involve measures of utility and equity. These performance measures were agreed upon after extensive study and solicitation of input from the transplant community, patients, government, and lay public. Utility measures include total (non-repeated) transplants, percent of transplanted patients who survive greater than 2 years, number of post-transplant life years, probability of receiving a transplant, and probability of dying on the waiting list. Equity measures include waiting time, differences in percent of status types transplanted by region, and local use of organs and its impact on organ donation. The large amount of complex data from these modeling efforts has been discussed and debated in many different forums, but most importantly within the committee structure set up by UNOS including the Liver and Intestinal Organ Transplantation Committee, the Patient Affairs Committee, and the Allocation Advisory Committee. These committees represent a broad spectrum of individuals interested in transplantation including transplant surgeons and physicians, nurses, patients, lawyers, ethicists, governmental representatives, and the lay public.

The data from the UNOS ULAM did not reveal a distribution scheme that, in the majority opinion of the Liver and Intestinal Organ Transplantation Committee, was superior to the current system. After much debate and deliberation, however, several changes to refine the current system were proposed to the UNOS Board of Directors. These proposals were issued for public comment on August 13, 1996. Public



forums were held in St. Louis September 25-16, 1996 and extensive public comment was received concerning these proposed changes. As a result of this input, a revised proposal was submitted by the Liver and Intestinal Organ Transplantation Committee to the UNOS Board that was unanimously approved on November 13, 1996.

We agree with the proposal to eliminate the Status 4 category and redefine Status 1 to include patients with acute fulminant liver failure, primary graft non-function within 7 days of transplantation, hepatic artery thrombosis within 7 days of transplantation, acute decompensated Wilson's disease, and pediatric liver transplant candidates with ornithine transcarbamylase (OTC) deficiency and those under age 12 with chronic liver disease in an intensive care unit. This clarification of the urgency status code definitions gives priority to the patients who, as a group, have the most urgent need. This proposal has widespread support nationally and includes a group of patients with excellent long-term survival if transplanted in a timely manner. There has been a misconception that patients with decompensated chronic liver failure are being disadvantaged and that a change in policy has been made to transplant patients with higher survival rates. The fact is that the major impetus for this change was to improve access to livers for patients with less than two weeks to live. It is true that this group has a higher survival rate than Status 2 patients with chronic liver disease, but this was not the driving force for change. As with any rule or guideline, there will be valid exceptions that do not fit within the clearly defined boundaries. There may be unusual cases where Status 2 patients rapidly decompensate and meet the criteria of less than two weeks to live. We support the suggestion that a regional or broadly based national committee be formed to consider exceptions to these criteria similar to the "Exceptional Case Review and Monitoring System" proposed for the minimum listing criteria.

We also agree with the development of more uniform minimal listing criteria and a regional peer review system for monitoring compliance. The implementation of uniform minimal listing criteria will be necessary to achieve more equitable access to organs for patients on the waiting list and will hopefully lead to more uniform waiting times. It will, at the very least, allow a more accurate comparison of waiting times without the variability of differing listing criteria. We strongly support the idea of a monitoring system to provide peer review of patients being listed to be certain that these criteria are implemented fairly and appropriately. We believe that the implementation of uniform minimal listing criteria and an effective peer review system must be in place prior to consideration of any wider sharing schemes than currently exist.

We have recounted some of the pertinent facts regarding the recent controversy over liver allocation to emphasize our support for the proposal that was approved by the UNOS Board and for the process that was used to arrive at this decision. We believe the improvements in the liver distribution and allocation policy are in the best interests of patients waiting for liver transplantation and balance utility and equity based on the analysis of the data available. We do not believe there is " . . . considerable unresolved controversy within the transplant community". On the contrary, the widespread support for this proposal among the liver transplant programs in the United States is evidenced by the signatures of 61 liver transplant program directors attached to this letter. There are a small number of programs who do not agree with the current system and the proposed revisions and have mounted a public relations campaign in the press, in Congress, and in the Executive Branch to try and influence public opinion outside the established system for change i.e. UNOS. We strongly disagree with this approach.

This brings us to what we believe is the only unresolved controversy concerning liver allocation and that is who determines allocation policy. When Congress established the Organ Procurement and Transplantation Network (OPTN), the Department of Health and Human Services was authorized to grant



the OPTN contract, currently held by UNOS, and to oversee the activities of the OPTN (section 372 of the Public Health Service Act). It has been the opinion of Congress, UNOS, and the transplant community that making and implementing allocation policy was the responsibility of UNOS. UNOS has a system of committees with defined roles and responsibilities that involve a broad spectrum of individuals with an interest in transplantation and the patients we serve. In the case of organ allocation policy, the UNOS Board of Directors receives input from several committees depending on the particular organ and issue of concern. It is a system that is responsive to change and has been shown to work. In fact, we believe the process by which liver allocation policy has been made, studied, and revised is an excellent example of how UNOS and its committees can consider a broad range of opinions on a controversial subject and arrive at a fair and equitable decision. We do not believe anyone has argued that these decisions are perfect or may not require revision in the future as circumstances change.

Furthermore, we are concerned with what appears to be a change in policy by HHS. Several of us in a meeting with Deputy Secretary Thurm were reassured that HHS had no desire to make or mandate organ allocation policy. He recognized that the issues were scientifically complex and were best decided within the committee and board structure of UNOS. Only if UNOS approved a policy that was clearly contrary to federal law or policy would HHS intervene. We respectfully request that this position be maintained.

In summary, we who represent a majority of the liver transplant programs and patients waiting for liver transplantation, urge you to recognize the authority and effectiveness of the current OPTN in resolving controversial issues concerning organ procurement, distribution, and allocation. UNOS has strong support within the transplant community and the impact of an attempt by HHS to determine policy without an overriding need will lead to an even stronger reaction from the entire transplant community than what has recently occurred in response to this threatened action. We urge you to maintain your previous policy of recognizing the authority of the OPTN to determine policy.

Thank you very much for allowing us the opportunity to express these opinions.

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American Medical Association

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**Council on Ethical
and Judicial Affairs**

1996-1997 Edition

Code of Medical Ethics

*Current Opinions with
Annotations*

*Annotations prepared by the
Southern Illinois University Schools of Medicine and Law*

Preface

This edition of *Current Opinions with Annotations* of the Council on Ethical and Judicial Affairs replaces all previous editions of *Current Opinions*. It is one component of the American Medical Association's Code of Ethics; the other components are the Principles of Medical Ethics, Fundamental Elements of the Patient-Physician Relationship, and the Reports of the Council on Ethical and Judicial Affairs. The Principles and Fundamental Elements are published in *Current Opinions with Annotations*. Reports are published separately.

The Principles of Medical Ethics are the primary component of the Code. They establish the core ethical principles from which the other components of the Code are derived. The Principles were revised most recently in 1980.

Fundamental Elements of the Patient-Physician Relationship enunciates the basic rights to which patients are entitled from their physicians.

Current Opinions with Annotations reflects the application of the Principles of Medical Ethics to more than 135 specific ethical issues in medicine, including health care rationing, genetic testing, withdrawal of life-sustaining treatment, and family violence. Much as courts of law elaborate on constitutional principles in their opinions, the Council develops the meaning of the Principles of Medical Ethics in its opinions. Accordingly, each opinion is followed by one or more roman numerals that identify the Principle(s) from which the opinion is derived. Each opinion is also followed by a list of annotations that reflect citations to the opinion in judicial rulings and the medical, ethical, and legal literature.

The Reports discuss the rationale behind many of the Council's opinions, providing a detailed analysis of the relevant ethical considerations.

All four components of the AMA's Code of Ethics need to be consulted to determine the Association's positions on ethical issues. In addition, the AMA's House of Delegates at times issues statements on ethical issues. These statements are contained in a separate publication, the *AMA Policy Compendium*. Because the Council on Ethical and Judicial Affairs is responsible for determining the AMA's positions on ethical issues, statements by the House of Delegates should be construed as the view of the House of Delegates but not as the ethics policy of the Association.

Medical ethics involve the professional responsibilities and obligations of physicians. Behavior relating to medical etiquette or custom is not addressed in *Current Opinions With Annotations*. The opinions that follow are intended as guides to responsible professional behavior, but they are not presented as the sole or only route to medical morality.

No one Principle of Medical Ethics can stand alone or be individually applied to a situation. In all instances, it is the overall intent and influence of the Principles

of Medical Ethics that shall measure ethical behavior for the physician. Council opinions are issued under its authority to interpret the Principles of Medical Ethics and to investigate general ethical conditions and all matters pertaining to the relations of physicians to one another and to the public.

The Council on Ethical and Judicial Affairs encourages comments and suggestions for future editions of this publication.

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patients who suffer unexpected cardiac death may be cannulated and perfused with cold preserving fluid (in situ preservation) to maintain organs. Both of these methods may be ethically permissible, with attention to certain safeguards.

(1) When securing consent for life support withdrawal and organ retrieval, the health care team must be certain that consent is voluntary. This is particularly true where surrogate decisions about life-sustaining treatment may be influenced by the prospect of organ donation. If there is any reason to suspect undue influence, a full ethics consultation should be required.

(2) In all instances, it is critical that there be no conflict of interest in the health care team. Those health care professionals providing care at the end of life must be separated from providers participating in the transplant team.

(3) Further pilot programs should assess the success and acceptability of organ removal following withdrawal of life-sustaining treatment.

(4) In cases of in situ preservation of cadaveric organs, the prior consent of the decedent or the consent of the decedent's surrogate decisionmaker makes perfusion ethically permissible. Perfusion without either prior specific consent to perfusion or general consent to organ donation violates requirements for informed consent for medical procedures and should not be permitted.

(5) The recipients of such procured organs should be informed of the source of the organs as well as any potential defects in the quality of the organs, so that they may decide with their physicians whether to accept the organs or wait for more suitable ones.

(6) Clear clinical criteria should be developed to ensure that only appropriate candidates, whose organs are reasonably likely to be suitable for transplantation, are considered eligible to donate organs under these protocols.

Issued June 1996 based on the reports "Ethical Issues in the Procurement of Organs Following Cardiac Death: The Pittsburgh Protocol" and "Ethical Issues in Organ Procurement Following Cardiac Death: In Situ Preservation of Cadaveric Organs," issued December 1994.

2.16 Organ Transplantation Guidelines. The following statement is offered for guidance of physicians as they seek to maintain the highest level of ethical conduct in the transplanting of human organs.

(1) In all professional relationships between a physician and a patient, the physician's primary concern must be the health of the patient. The physician owes the patient primary allegiance. This concern and allegiance must be preserved in all medical procedures, including those which involve the transplantation of an organ from one person to another where both donor and recipient are patients. Care must, therefore, be taken to protect the rights of both the donor and the recipient, and no physician may assume a responsibility in organ transplantation unless the rights of both donor and recipient are equally protected. A prospective organ transplant offers no justification for a relaxation of the usual standard of medical care for the potential donor.

- (2) When a vital, single organ is to be transplanted, the death of the donor shall have been determined by at least one physician other than the recipient's physician. Death shall be determined by the clinical judgment of the physician, who should rely on currently accepted and available scientific tests.
- (3) Full discussion of the proposed procedure with the donor and the recipient or their responsible relatives or representatives is mandatory. The physician should ensure that consent to the procedure is fully informed and voluntary, in accordance with the Council's guidelines on informed consent. The physician's interest in advancing scientific knowledge must always be secondary to his or her concern for the patient.
- (4) Transplant procedures of body organs should be undertaken (a) only by physicians who possess special medical knowledge and technical competence developed through special training, study, and laboratory experience and practice, and (b) in medical institutions with facilities adequate to protect the health and well-being of the parties to the procedure.
- (5) Recipients of organs for transplantation should be determined in accordance with the Council's guidelines on the allocation of limited medical resources.
- (6) Organs should be considered a national, rather than a local or regional, resource. Geographical priorities in the allocation of organs should be prohibited except when transportation of organs would threaten their suitability for transplantation.
- (7) Patients should not be placed on the waiting lists of multiple local transplant centers, but rather on a single waiting list for each type of organ. (I, III, V)

Issued prior to April 1977.

Updated June 1994 based on the report "Ethical Considerations in the Allocation of Organs and Other Scarce Medical Resources Among Patients," issued June 1993. In addition, the 1986 Report of the U.S. Task Force on Organ Transplantation is an excellent resource for physicians involved in organ transplantation.

Journal 1987 Discusses the issue of the right of the individual to consent to organ removal and then examines the doctrine of informed consent as it is applied in the context of live organ donation. Evaluates the extent to which removal of non-regenerative organs disrupts the basis for application of the traditional informed consent model. Additional attention is devoted to special concerns regarding consent in cases of children and incompetent patients, with consideration of the role of judicial review in these types of cases. Quotes Opinion 2.15 (1986) [now Opinion 2.16]. Adams, *Live Organ Donors and Informed Consent: A Difficult Minuet*, 8 *J. Legal Med.* 555, 560-61 (1987).

-
- 2.161 Medical Applications of Fetal Tissue Transplantation.** The principal ethical concern in the use of human fetal tissue for transplantation is the degree to which the decision to have an abortion might be influenced by the decision to donate the fetal tissue. In the application of fetal tissue transplantation the following safeguards should apply: (1) the Council on Ethical and Judicial Affairs' guidelines on clinical investigation and organ transplantation are followed, as they pertain to the recipient of the fetal tissue transplant (see Opinion 2.07, Clinical Investigation, and Opinion 2.16, Organ Transplantation Guidelines); (2) a final decision regard-

2.16

2.165

~~Handwritten signature~~

Source

Organ and Tissue Donation

A Reference Guide for Clergy

2nd Edition
1995

SEOPF
UNOS

Summary Statements of Various Religious Groups

AME & AME ZION (African Methodist Episcopal)

Organ and tissue donation is viewed as an act of neighborly love and charity by these denominations. They encourage all members to support donation as a way of helping others.

AMISH

The Amish will consent to transplantation if they believe it is for the well-being of the transplant recipient. John Hostetler, world renowned authority on Amish religion and professor of anthropology at Temple University in Philadelphia, says in his book, Amish Society, "The Amish believe that since God created the human body, it is God who heals. However, nothing in the Amish understanding of the Bible forbids them from using modern medical services, including surgery, hospitalization, dental work, anesthesia, blood transfusions or immunization."

ASSEMBLY OF GOD

The Church has no official policy regarding organ and tissue donation. The decision to donate is left up to the individual. Donation is highly supported by the denomination.

BAPTIST

Though Baptists generally believe that organ and tissue donation and transplantation are ultimately matters of personal conscience, the nation's largest protestant denomination, the Southern Baptist Convention, adopted a resolution in 1988 encouraging physicians to request organ donation in appropriate circumstances and to "...encourage voluntarism regarding organ donations in the spirit of stewardship, compassion for the needs of others and alleviating suffering." Other Baptist groups have supported organ and tissue donation as an act of charity and leave the decision to donate up to the individual.

BRETHREN

While no official position has been taken by the Brethren denominations, according to Pastor Mike Smith, there is a consensus among the National Fellowship of Grace Brethren that organ and tissue donation is a charitable act so long as it does not impede the life or hasten the death of the donor or does not come from an unborn child.

BUDDHISM

Buddhists believe that organ and tissue donation is a matter of individual conscience and place high value on acts of compassion. Reverend Gyomay Masao, president and founder of the Buddhist Temple of Chicago says, "We honor those people who donate their bodies and organs to the advancement of medical science and to saving lives." The importance of letting loved ones know your wishes is stressed.

CATHOLICISM

Catholics view organ and tissue donation as an act of charity and love. Transplants are morally and ethically acceptable to the Vatican. According to Father Leroy Wickowski, Director of the Office of Health Affairs of the Archdiocese of Chicago, "We encourage donation as an act of charity. It is something good that can result from tragedy and a way for families to find comfort by helping others." Pope John Paul II has stated, "The Catholic Church would promote the fact that there is a need for organ donors and that Christians should accept this as a 'challenge to their generosity and fraternal love' so long as ethical principles are followed."

**ABSTRACT FORM FOR:
THE AMERICAN SOCIETY OF TRANSPLANT PHYSICIANS**

15th Annual Scientific Meeting
May 10-14, 1997

**DEADLINE FOR RECEIPT OF ABSTRACTS:
January 15, 1997**

(For office use)

Type abstract below. Be sure to stay within border.

REGIONAL WAITING TIME DIFFERENCES: A UNOS STUDY OF THE LIVER WAITING LIST

Geographic variability in pretransplant waiting times continues to be an area of debate in transplantation. The underlying reasons for variability are complex, however contributing factors include regional organ recovery rates, waiting list sizes and candidate characteristics such as first or repeat transplant, medical urgency status, blood type, race and age. In order to examine variability in liver waiting times, all primary registrations added to the waiting list between 1993 and 1995 (N=18,993) were analyzed. For each UNOS region, and for the U.S. overall, a ratio (R/T) of the number of registrations to the number of organs recovered and subsequently transplanted was calculated. R/Ts were compared with regional median waiting times (MWT), stratified according to UNOS medical urgency status at listing and at time of transplant (status at listing/status at transplant) as shown below. Status 3 and 4 patients were combined into one group.

Region	R/T	1/1	2/1	2/2	3,4/1	3,4/2	3,4/3,4	Overall
A	1.14	4	8	5	61	57	82	64
B	1.51	4	7	11	56	70	103	71
C	1.58	3	**	8	**	88	144	113
D	2.15	4	10	17	89	126	321	238
E	2.28	4	22	27	80	128	172	139
F	2.29	4	14	18	82	100	202	162
U.S.	2.64	4	12	15	95	127	243	164
G	3.05	3	11	13	77	125	323	182
H	3.18	5	10	20	136	112	279	193
I	3.50	2	10	13	91	158	+	278
J	4.19	6	13	53	235	215	580	423
K	4.72	5	17	56	122	182	862	290

+ median is not estimable; ** <10 registrations in stratum

Waiting times across regions for the most medically urgent patients were relatively uniform. Regional MWTs were longest and variability was largest when patients were both listed and transplanted as status 3 or 4. For such patients, MWTs were particularly long in two UNOS regions, where corresponding R/Ts were also very high. This suggests that waiting times for those patients and regional R/Ts could be reduced through increased organ recovery, increased interregional organ sharing, and/or redistribution of waiting list sizes to be more in proportion to local organ availability.

Maureen A. McBride, Mary D. Ellison, Charles F. Shield, Leah E. Bennett, H. Myron Kauffman, United Network for Organ Sharing, Richmond, Virginia

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A. TOPIC CATEGORIES (Check One)

- A. Immunobiology
1. T cell activation/B cell activation
 2. Allorecognition/Antigen processing and presentation
 3. Cytokines/Chemokines
 4. Chronic rejection
 5. Experimental immunosuppression
 6. Tolerance
 7. Animal models
 8. Mediators of Tissue Injury
 9. Xenotransplantation
 10. Others
- B. New Immunosuppression - Clinical Trials
- C. Kidney Transplantation - Clinical
- D. Pancreas and Kidney - Pancreas Transplantation - Clinical
- E. Intrathoracic Organ Transplantation - Clinical
- F. Liver and Intestinal Transplantation - Clinical
- G. Bone Marrow Transplantation
- H. Histocompatibility and Immunogenetics
- I. Pediatric Transplantation - All Organs
- J. Organ Procurement, Preservation, Allocation
- K. Ethics and Economics

B. Young Investigator Travel Awards

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- Name and signature of sponsoring ASTP member:

Print Name

Signature

C. International Young Investigator Awards

- Submitted for consideration of award.

D. Conflict of Interest Statement

I certify that potential conflicts of interest will be disclosed at the time of the oral or poster presentation of the abstract. All potential conflicts of interest will be detailed in a separate letter to the ASTP Program Committee Chair, 6900 Grove Road, Thorofare, NJ 08086, USA

Signature

**NATIONAL TRANSPLANT ACTION COMMITTEE
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(617) 566-3430**

*Files
Liver
Transplants*

April 14, 1997

Mr. Chris Jennings
Office of Domestic Policy
The White House
Washington, DC 20500

Dear Chris,

Thanks for meeting with me on Wednesday (4/9/97) to discuss some of the ongoing concerns of the National Transplant Act. The original framers of the transplant legislation hoped to establish a fair and equitable national system for all patients needing treatment.

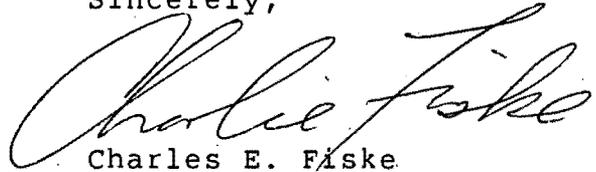
The "system" has come a long way since 1984 when there were a handful of medical facilities offering transplant services. A single national system would offer hope to all patients no matter where they lived in the country. Some of the recent deliberations regarding allocation have highlighted ongoing problems. The confusion between the role of the Transplant Network and the contractor (UNOS) regarding the formulation of public policy has led to the current debate within the transplant community. The contractor wants little Federal oversight and feels it's most knowledgeable to formulate rules and public policy. We feel that Federal oversight is essential if we are to assure all citizens that the system is fair. The contractor declares itself to represent the "transplant community" yet its representation is disproportional and doesn't speak for the patient community. It's difficult to assume that the contractor on one hand be a membership group that develops policy and on the other oversee the implementation of rules and policy regulations. Throughout all of these presenting problems the shortage of organs remains and causes great concern to the many waiting patients.

Thanks for taking the time to review some of the issues. Hopefully policies can be developed and implemented that will achieve the goals included in the original legislation. The shortage of organs remains. As I'd mentioned, I'd like to meet with you during the coming week at a time that's convenient for you, specifically to discuss the shortage problem. If donation

could be improved, then the issues we currently face would have some resolution. This would allow the Department to address policy rules that help to make the system fair and equitable. I'll give your office a call this coming week regarding the availability of time during the following week.

Again thanks for taking time to meet with us last week and I look forward to speaking.

Sincerely,

A handwritten signature in cursive script that reads "Charles E. Fiske". The signature is written in dark ink and is positioned above the printed name.

Charles E. Fiske

PS. Enclosed is the proposed change to the Transplant Act that's been already submitted to the Department and was formulated by NTAC and Board president Craig Irwin.

Enc. 1

GOVERNING ORGAN TRANSPLANTATION

**PROPOSED CHANGES TO THE
NATIONAL ORGAN TRANSPLANT ACT**

BY

**NATIONAL TRANSPLANT ACTION
WASHINGTON, D.C.**

GOVERNING ORGAN TRANSPLANTATION

**PROPOSED CHANGES TO THE
NATIONAL ORGAN TRANSPLANT ACT**

**PREPARED BY
NATIONAL TRANSPLANT ACTION
WASHINGTON, D.C.**

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National Transplant Action (NTA) is a non-profit, publicly supported initiative promoting informed consumerism among patients and families involved with organ and tissue transplantation. NTA fosters consumerism through: enhancing education; assisting with information access about medical treatment, financial aid, and social services; promoting legal, civil, and human rights respecting transplantation and donation; and encouraging mutual support and unity by promoting information exchange and communication.

I. Executive Summary

National Transplant Action is proposing amendments to the National Organ Transplant Act that would centralize the rulemaking and oversight of the Organ Procurement and Transplantation Network through the establishment of the National Organ Transplant Governing Board. The change would consolidate the patchwork of the various rule making bodies in the current system into a single authority subject to Congressional review. Our proposal also eliminates appropriations for the operation and oversight of the OPTN and reduces federal spending by \$3.5 million annually (see Fiscal Impact).

Congress enacted the National Organ Transplant Act in 1984, in order to stimulate rational and fair policy making in the field of organ transplantation and to develop a fair and efficient system for the sharing of donated organs. The Act established the Organ Procurement and Transplantation Network (OPTN) and commissioned a National Task Force to examine and report on many of the key issues in the field of transplantation. The Act was amended by Congress in 1988 and 1990. Congress held hearings on the Act in 1993 with both chambers approving bills further amending the 1984 legislation. However, the 103rd Congress adjourned sine die in 1994 without reconciling the separate bills.

In addition to the Congress, a number of other entities have participated in the promulgation of national organ transplant policies, rules, and regulations. Two separate divisions of the U.S. Department of Health and Human Services are involved in rulemaking. The Health Care Financing Administration (HCFA) has primary oversight for reimbursement and coverage of organ transplantation under the federal Medicare and Medicaid programs. Approximately 80-90% of all kidney transplants are paid for by Medicare through the End Stage Renal Disease Program. The Health Resources and Services Administration of the Public Health Service has been given primary jurisdiction over the OPTN. The U.S. Department of Defense and Department of Veterans Affairs also have roles in organ transplantation policy through the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) and the Veterans Administration hospital system.

The Act requires that the Public Health Service contract with a private, non-profit organization, to operate the OPTN. The United Network for Organ Sharing (UNOS), based in Richmond, VA. has been the only contractor to date.

For all intents and purposes, UNOS has been the chief author of transplant rules and regulations in the United States. UNOS is a membership organization comprised almost exclusively of the hospitals and medical organizations directly involved in organ procurement and transplantation.

This patchwork of authority and oversight has resulted in considerable controversy. Section 273 of 42 U.S.C. requires that Organ Procurement Organizations (OPOs) must be members of the OPTN and subject to its rules and regulations in order to be reimbursed by Medicare. Because of this requirement, the Department of Health and Human Services published a public notice in 1989 declaring that the rules and regulations promulgated by the private contractor, UNOS, were not enforceable unless approved by the Department. The Congress expressed its concern over this development in 1990 and Members of the House of Representatives were further distressed to hear testimony in 1993 that final rules and regulations had still not been approved by the Department. To date, a Notice of Proposed Rule Making has been published but no final rules have been approved.

The most significant policy issue facing the OPTN is the allocation and distribution of organs for transplantation. UNOS made major changes to liver allocation rules in 1991 which have resulted in a system of local primacy in transplantation. This debate has pitted the smaller transplant centers, which because of their numbers dominate UNOS policy making, against the larger regional centers which serve the bulk of transplant patients. The objective of the Act: to create a fair and efficient system of organ procurement and transplantation, has become lost in this debate of lives vs. livelihoods.

Therefore, NTA is proposing that the National Organ Transplant Act be amended so that responsibility for national organ transplant policy and the rules and regulations of the OPTN are vested in the National Organ Transplant Governing Board. The objective of the Board is not to create an additional layer of government, but rather to synthesize the current patchwork of rulemaking and oversight into a single authority readily available for Congressional review. Congress has been clear in its intention that the OPTN be self governing. That does not imply that the OPTN governing authority and the OPTN contractor be one and the same as the current system might suggest. Instead, we propose that the governing and the operation of the OPTN be two separate and distinct functions.

The Board would be comprised of members of the public as well as medical

professionals and would be selected in such a manner as to maintain objectivity, balance the needs and concerns of all involved with transplantation, and uphold the public interest. The objective of the Board would be to promulgate and enforce the rules and regulations of the OPTN consistent with Congressional mandates.

The proposed changes would eliminate appropriations for the operation and oversight of the OPTN resulting in a reduction of \$3.5 million in federal spending. The Board would review the current fee structure and other options available in the private sector to fund the operation of the Board and the OPTN. The role of the Public Health Service in this area could be virtually eliminated and administrative costs reduced. The initial operation of the Board would be financed through a government loan. The future operation of the Board, the OPTN, and the loan repayment would be financed by patient registration fees, user fees, or other such sources of revenues to be developed by the Board.

Under our proposal, the Board would be removed from the bureaucratic policies that have resulted in the current 6 year odyssey on the part of the Public Health Service to try and approve the OPTN rules already promulgated by the private contractor, UNOS. Although the Board would necessarily be required to facilitate public input in the formulation of organ procurement and transplantation policy, it is our intent that the Board be exempt from those Executive Department regulations that would delay timely decision making.

The establishment of the National Organ Transplant Governing Board would facilitate the promulgation of fair and equitable rules, regulations, and policies. This private/public effort would address the jurisdictional questions that have prevented timely and orderly rulemaking and avoid the Constitutional issues inherent in the current system that seems to permit a private entity to formulate federal regulations. Finally, the Board would permit the valuable input from patients, families, and the public at large that is currently lacking while offering budget efficiencies for the federal government.

II. Legislative History

The National Organ Transplant Act (the Act) was enacted in 1984 (P.L. 98-507). Its purpose was to "support development of a rational and fair national health care policy regarding organ transplantation." The Act established the Organ Procurement and Transplantation Network (OPTN) and vested the Public Health Service with the responsibility of overseeing the OPTN. The actual operation of the national network was to be contracted out to a private entity. The Act created a National Task Force on Organ Procurement and Transplantation that was charged with a number of responsibilities including the development of recommendations that would lead to a "truly national, coordinated mechanism for efficient distribution of all available organs."

As part of the legislation, Congress attempted to define the intended roles of the public and private sectors in organ transplantation. It was the sense of Congress that a strong initiative already existed in the private sector and that the role of the government was to "stimulate" the private effort. In addition to the OPTN and the Task Force, a great deal of importance was placed on the role of the American Council on Transplantation (a private, non-profit organization established in 1983 with the financial assistance of the Department of Health and Human Services) in the promulgation of national transplant policy. Also, Congress was depending upon the recommendations of the Task Force in the future development of national transplant policy. (See Senate Report No. 98-382 and House Conference Report No. 98-1127, U.S. Code Cong. and Adm. News, p.3975)

The Act was amended in 1988 (P.L. 100-607). Congress reaffirmed that "the Organ Procurement and Transplantation Network (OPTN) was created in the 1984 Act in order to facilitate an equitable allocation of organs among patients." However, concern was expressed that "despite the cumulative legislative efforts coupled with those of public and private groups, there is still an organ shortage, and there are still inefficiencies and inequalities in the organ procurement system."

The 1988 Amendments also clarified the roles of Organ Procurement Organizations (OPOs) and the OPTN. The OPOs were to be responsible for "allocating organs equitably among the patients who are in need of a transplant." The OPTN was to assist the OPOs in that process. It was also the

sense of Congress that the OPTN was to have broad authority and responsibility over public policy in organ transplantation. "The OPTN's responsibilities are great and the purpose of the Act will be served only if the policies of the OPTN are sound and are soundly developed. The allocation of organs may well be a life-or-death decision for patients. The OPTN...should resolve any issues regarding the fair and effective distribution of organs. Patient welfare must be the paramount consideration."

While expanding the responsibilities of the OPTN, Congress also mandated that the OPTN establish procedures to give members of the public an opportunity to comment on OPTN policies. It further mandated that the Public Health Service develop a process for the receipt and evaluation of public input. "It is the intent that the OPTN undertake this process (of soliciting public input) for its existing criteria and that it do so whenever changes in the criteria are under consideration. Congress also urges the OPTN to arrange for public comment at least once a year, even if no changes are proposed, and expects the Department of Health and Human Services to follow closely and review these criteria. The OPTN should replicate as closely as possible the process followed by such agencies as the Health Care Financing Administration in promulgating regulations, including the use of a public hearing on issues of major consequence and potential controversy." (See House Report Nos. 100-761, 100-778, 10070, Senate Report Nos. 100-133, 100-310, 100-552, 100-476, and House Conference Report No. 100-1055, U.S. Code Cong. and Adm. News, p.4167)

The most recent major changes to the Act came as a result of the Transplant Amendments Act of 1990 (P.L. 101-616). While Congress expressed significant concerns about the operation of the OPTN and the oversight responsibility of the Public Health Service it also continued to clarify the omnipotent role of the OPTN.

Congress once again stated that "the OPTN, in addition to maintaining the single national list of all patients waiting for an organ transplant, is also charged with setting much of national transplant policy." Yet, Congress also reported that "In studying the existing board and its performance...the (Congress) believes change is necessary, but is reluctant to force any specific model for changing the structure of the board." It was further hoped that "greater opportunities will be provided to members of the public and voluntary health organizations to serve in leadership positions on the board."

Congress was "especially troubled" over the lack of enforceable national

regulations resulting from a 1989 public notice by the Department of Health and Human Services. The 1989 notice mandated that OPTN policies be reviewed and receive formal approval of the Secretary in order to be enforced. The resulting policy vacuum was declared "inexcusable." It was the hope of Congress that the Secretary take a more personal interest in the OPTN and be at the "forefront of insuring its success."

Congress attempted to improve the rule making structure by lowering the minimum qualifications of the OPTN contractor in order to "provide the Secretary with the opportunity to seek out the best possible potential applicants for this critical role." Congress made it clear that the 1990 amendments "reflect deep concern on the part of (Congress) in the manner in which the OPTN has functioned. It is the intent that this bill will assist a midcourse correction." (See Senate Report No. 101-530, 1990 U.S. Code Cong. and Adm. News, p. 4625).

III. Commentary

It is clearly evident from the legislative history that an efficient and equitable organ allocation system through the National Organ Transplant Act has been the ongoing objective of the Congress. As part of the 1988 amendments to the Act, Congress was careful to remove any statutory bias respecting the important question of criteria for the proper distribution of organs among patients. Prior to the change, the OPTN was only required to assist OPOs in the distribution of organs "which cannot be placed within the service areas of the organizations." Congress was concerned that this language would be interpreted to give preference to the local allocation of donated organs and removed the wording from the Act. Despite Congressional intentions, local priority in the distribution of organs is the prime issue of contention today. During its deliberations on the Act in 1993, Congress heard complaints from patient representatives and transplant centers that the current system of organ allocation is not fair and is geographically biased.

The National Organ Transplant Act clearly mandates a "national" system of allocating donated organs. The system is to be efficient and fair. Today, the

system is geographically biased with organ allocation based upon local priority regardless of the medical status of the recipient. The system is also biased based upon agreements between OPOs and hospitals performing organ transplants. Despite widespread dissatisfaction with the current system there has been no attempt by the OPTN contractor, the United Network for Organ Sharing (UNOS) to correct this situation in a satisfactory manner. UNOS has gone as far as to suppress criticism and efforts to change the system by withholding vital information useful in evaluating the current system and any possible future modifications.

Congress has made it equally clear that the responsibility for promulgating national organ transplant policy should be that of the OPTN. However, nowhere is it expressed or implied that the "OPTN" and the "OPTN contractor" be one in the same. Yet, UNOS corporate by-laws constitute the national public policy on most transplant issues, including the important matter of organ allocation. Congress has also expressed a lack of confidence in the capabilities of the current OPTN contractor, UNOS to successfully carry out the objectives of the National Organ Transplant Act. Congress has expressed equal disappointment in the oversight on the part of the Department of Health and Human Services.

The Department of Health and Human Services has failed to give the necessary attention to the OPTN. In 1989 the Secretary published a notice that no rule or regulation of the OPTN was binding unless approved by the Secretary. In 1990, Congress declared as "inexcusable" the "policy vacuum" resulting from this action. Members continued to express concern during hearings on the Act in 1993 as the Secretary had still failed to promulgate rules. As of May 1995, over 5 years has passed since the Secretary's original public notice and final rules still remain to be approved. As a result, the OPTN functions based upon voluntary compliance with the UNOS corporate by-laws.

Despite clear direction and mandates from Congress - the National Organ Transplant Act is failing.

In theory, the Act should work. Congress has clearly stated its intentions and public policy objectives. It should be the responsibility of the OPTN to promulgate national organ transplant rules and regulations to meet the national objectives. Public policy decisions should also be timely and serve the best interests of patients, donor families, and the public at large.

The Act won't work in practice for a variety of reasons. First, the OPTN

is a membership organization. As such, decision making has centered on the membership. That membership is mainly institutional:

Group	No. of Members
Transplant Centers	275
Consortium Members	4
Independent OPOs	51
Independent Tissue Typing Labs	50
Voluntary Health Organizations	10
General Public Members	10
Medical/Scientific Organizations	26
TOTAL	<u>426</u>

(Source: 1994 UNOS Annual Report)

Despite the intent of Congress to the contrary, only 20 of the 426 (4.7%) members of the OPTN are members of the public or voluntary health organizations. UNOS by-laws go as far as to explicitly limit the number of voting members in these categories to 12 each. This institutional bias is reflected in the makeup of the OPTN board of directors, which is chosen by the membership. Of the 37 members of the OPTN board of directors, 19 are physicians or surgeons, 10 represent OPOs, tissue typing labs, or other health care institutions or organizations, and only 8 (21.6%) members are from the general public. And, those public members are chosen by the institutionally dominant members of UNOS. With one exception all the officers of the OPTN and all of the 10 Regional Councilors are physicians and surgeons representing transplant facilities.

UNOS is a membership organization comprised almost entirely of representatives from transplant facilities and the medical community. As the OPTN contractor that medical bias is not troublesome and in fact might be beneficial. However, in promulgating national policy, the OPTN/UNOS board of directors makes many decisions affecting the welfare of transplant centers, especially with respect to the allocation of donated organs: a scarce and valuable resource. A serious conflict of interest is implicit in the current structure given the scope of the decisions made by the UNOS board of directors. It is reasonable to assume that important UNOS board decisions will be influenced by the possible impact those decisions will have on board members and the medical facilities that they represent.

The OPTN board of directors is in the enviable position of policymaker, overseer, benefactor, and contractor. The OPTN contractor's position has been

strengthened by the lack of oversight and attention by the Department of Health and Human Services. The Secretary has made no effort to address current conflicts regarding national transplant policy and the concerns of patients, donor families, and the public at large have been ignored. The Secretary has failed to publish final OPTN rules and the proposed rule published in September 1994 was nothing more than the by-laws of the institutional membership of the OPTN contractor. It is very evident that the private sector, OPTN contractor UNOS, has the upper hand in the current structure.

Finally, Congress has developed contradictory legislation and direction regarding the OPTN's role in national transplant policy. On one hand, Congress has clearly stated throughout the history of the National Organ Transplant Act that the OPTN should have broad powers and responsibilities. Section 274(b)(1)(B)(ii) of the Public Health Service Act mandates that the OPTN organize its committees and chairpersons in such a manner as to "ensure continuity of leadership for the board." On the other hand, Congress amended the Act in 1990 by lowering the minimum requirements for the OPTN contractor in order to give the Secretary the flexibility to "seek out the best possible potential applicants for this critical role."

These Congressional mandates are mutually exclusive as long as the OPTN contractor has both the responsibility for promulgating national policy as well as operating the OPTN under contract with the government. The "continuity of leadership" is meaningless if the Secretary contracts with a different private entity through the lowered contractor requirements. If a new contractor is chosen to operate the OPTN, then a change in public policy could certainly follow.

IV. Recommendations

In order to achieve the Congressional objectives there must be a "decoupling" of the public policy making function of the OPTN from the contractor function. The objective of the OPTN is an efficient and equitable system of organ procurement and distribution. That objective will be difficult to achieve as long as those promulgating national policy stand to gain or lose

financially or professionally by the outcome of their decisions.

National transplant policy should be decisive, timely, and serve the public interest. It's noteworthy that when Congress bestowed rule making authority with the OPTN in the 1984 Act, it was also expected that both the National Task Force on Organ Procurement and Transplantation and the American Council on Transplantation would have significant roles in the promulgation of national policy. Neither of those entities exist today.

NTA proposes that the public policy function of the OPTN be performed by a governing board. **The National Organ Transplant Governing Board** should consist of members of the public and the medical community and selected in such a manner as to ensure that the public interest is served. The professional members should be selected by the peers in their respective fields. The public members would be selected by the Executive Branch either through the Office of the President or the Secretary of Health and Human Services. Nominations for the public members would be solicited and special emphasis given to selecting individuals who were either transplant recipients or family members of recipients or organ donors.

The Board would be given the statutory authority for carrying out the objective of the National Organ Transplant Act and promulgating the rules and regulations of the OPTN. The Board would also be responsible for addressing other important issues in transplantation. It would develop the parameters of the OPTN contract and the operation of the OPTN would continue to be performed by a private entity. The Board would review and approve all fees associated with the operation of the OPTN and develop a private sector source of revenues for the operation of the Board and the OPTN.

The role of the Department of Health and Human Services in this area would be greatly diminished or eliminated. The Board would provide the oversight sought by the Secretary in the 1989 public notice requiring federal government approval of all OPTN rules and regulations. Therefore, the Board would be required to comply with certain mandates such as the Administrative Procedures Act. It is intended that the Board conduct itself in an open manner and freely permit input from the public as well as the medical community. In promulgating rules and regulations adequate public notice would be required. The Board would conduct hearings if deemed necessary. The Secretary of Health and Human Services would be notified in writing of any final rule and given a period of 30 days to respond after which the Board rule would go into effect. Also, as

the Board would develop private revenue sources for its operation and that of the OPTN it is proposed that its rules and policies be exempt from federal fiscal oversight.

We believe that this structure will serve to address the concerns expressed by Congress in the current system and facilitate achieving the objectives of the National Organ Transplant Act. Congress has clearly stated its belief that change is necessary. This proposal creates a fair, open, and unbiased process for developing an efficient and equitable system of organ procurement and distribution by eliminating the institutional predominance in the current OPTN structure. The objective of the Board is a process of promulgating national policy that overcomes the concerns expressed by Congress about the board of the current OPTN contractor. This process addresses the lack of oversight and attention on the part of the Department of Health and Human Services and vests authority and responsibility for the OPTN in a private/public entity.

Finally, the establishment of the Board overcomes the contradictory directives from Congress in 1990. This proposal facilitates "greater continuity in leadership and increased public accountability" while at the same time providing "the opportunity to seek out the best possible applicants" for the critical role of operating the OPTN.

V. Fiscal Impact

We believe that the creation of the Board will result in significant budget efficiencies. The role of the Public Health Service in this area would be virtually eliminated therefore reducing funding levels in the PHS Administrative budget (est. \$700,000/year). The Board would also be responsible for developing its own private sources of funding as well as private sources for operating the OPTN (current OPTN appropriation: est. \$2.65 million/year). The total reduction in federal spending as a result of this proposal is about \$3.35-3.5 million.

It will be the responsibility of the Board to develop the private revenue sources. It is anticipated that the most likely sources will be user fees,

patient registration fees and OPTN membership fees currently levied by UNOS. Patient registration fees already represent a significant portion of the operating revenues for UNOS. As the OPTN contractor would be relieved of the role for promulgating regulations the Board would need to review all UNOS revenue sources and make any necessary changes to the manner in which those resources are allocated.

It is important to note that the current UNOS fee structure was established without the explicit approval of Congress. Furthermore, there is no fiscal oversight to ensure that the funds generated by UNOS for operating the OPTN are used consistently with the purposes of carrying out the mandates of the Act. In a 1990 report to Congress, Apt Associates of Cambridge, MA. reported that "The membership fees and patient registration fees, are directly related to the OPTN contract; they are not a separate line of business for the corporation (UNOS). None of these fees could be collected by UNOS if another corporation held the OPTN contract...there is no other instance where the government, by awarding a contract, gives a corporation authority to compel desperately ill patients to pay over \$200.00 apiece to that contractor, to use as it wishes without direct government oversight."

We estimate that 1995 UNOS revenues from patient registration fees will be \$12-15 million. This does not include other membership fees levied by UNOS. With careful scrutiny and oversight we believe that the OPTN can operate more efficiently and cost effectively. Given the opportunity and the Congressional authority, the resources are available for the Governing Board to develop a funding plan based upon private revenue sources and eliminating the need for future government appropriations.

We propose that the federal government extend a loan to the Governing Board to commence its initial operations. The Board would then have a 2-year period to develop the private resources needed to fund the operations of the Board, the operations of the OPTN, and repayment of the federal loan.

PROPOSED LEGISLATIVE OUTLINE

NATIONAL ORGAN TRANSPLANT GOVERNING BOARD

The following proposed outline is intended to amend 42 United States Code, Section 274:

I. Not later than 180 days after the approval of the Congress, the Secretary shall establish the National Organ Transplant Governing Board (hereinafter referred to as the Board), to be composed of 27 members and consist of:

a. 12 members of the public who are not associated with any hospital, physician's clinic, OPO, or other medical facility participating in the OPTN, with one member from each of the 10 current regions of the OPTN and 2 members at large. The public members shall be selected by the President (or the Secretary) which special consideration given to the selection of transplant recipients or family members of transplant recipients or organ donors.

b. 11 members selected by the OPTN contractor board of directors and consisting of the following:

1. 4 members of the OPTN representing facilities performing organ transplants with one representative from each of the member: kidney transplant programs, liver transplant programs, heart transplant programs, and lung/heart lung transplant programs,

2. 2 at large members selected from among the 25 largest OPTN member transplant facilities as ranked according to the total number of transplant procedures performed in 1994,

3. 2 members representing OPTN member organ procurement organizations,

4. 1 member representing OPTN member independent tissue typing labs,

5. 2 members representing OPTN member voluntary health organizations.

c. ex-officio members:

1. the Chairman of the U.S. Senate Committee on Labor and Human Resources, the Chairman of the U.S. House of Representatives Committee on Commerce, the Surgeon General of the United States, and the Administrator of the Health Care Financing Administration, or their designees, shall serve as ex-officio members of the Board.

d. elected or appointed members of the Board described in I(a) and (b) shall serve a term of 3 years with 1/3rd of the terms expiring each year.

1. Prior to the expiration of the terms of office of the initial members of the Board, an election shall be held under rules adopted by the Board (pursuant to Section III(c)) of the members to succeed such initial members.

2. Any vacancies in the Board shall be filled consistent with the original appointment

II. Each member of the Board who is not an employee or an officer of the United States shall be compensated for each day during which such member is engaged in the actual performance of their duties as a member of the Board as well as reimbursement for travel expenses while away from home in the performance of duties for the Board.

III. The Board shall propose and adopt rules to effect the purposes described in the National Organ Transplant Act (P.L. 98-507 as amended Nov. 4, 1998, P.L. 100-607; Nov. 16, 1990, P.L. 101-616) with respect to the operations and regulations of the Organ Procurement and Transplantation Network. The rules of the Board, as a minimum, shall:

a. provide for the operation of the OPTN by contract with a private non-profit entity that has expertise in organ procurement and transplantation.

b. establish for the equitable and efficient distribution of donated organs for transplantation in accordance with established medical criteria.

1. no later than 1 year after the establishment of the Board, promulgate and implement rules providing for the distribution of donated organs to the most medically appropriate individual without consideration of geographic location taking into consideration organ viability and costs of cross-matching.

c. establish fair procedures for the nomination and election of members to the Board and assure fair representation in such nominations and elections. Such rules shall provide that, exclusive of ex-officio members, no less than 1/2 of the membership of the Board shall at all times be comprised of the public representatives and that the public representatives shall be subject to the approval of the President (or Secretary) to assure that no one of them is associated with any hospital, physician's clinic, OPO, or other medical facility participating in the OPTN.

d. provide for the operation and administration of the Board, including the selection of a Chairman from among the members of the Board, the compensation of the members of the Board, the appointment and compensation of such employees, attorneys, and consultants as may be necessary or appropriate to carry out the Board's function under this section.

e. appoint advisory committees with expertise in organ transplantation, histocompatibility, organ procurement and preservation and any other medical and technical matters as may be necessary for the Board to carry out its function.

f. provide for reasonable fees and charges that may be necessary or appropriate to defray the costs and expenses of operating the OPTN and

administering the Board.

1. the Board shall review all patient registration fees, membership fees, and other fees currently levied by the OPTN contractor and directly related to the operation of the OPTN and make any changes in the amount, allocation, or usage in those fees

2. no later than 2-years after the date of enactment submit to the Congress a plan for the private funding of the Board and the OPTN.

IV. The Board shall have the authority to promulgate all rules and regulations of the OPTN. The Board will notify the Secretary of all rules and regulations established by the Board, such rules to be considered as approved if the Secretary does not provide otherwise prior to the 30 day period beginning on the date on which the rules and regulations are submitted to the Secretary.

V. The Board will report to Congress every two years on the status and operation of the OPTN.

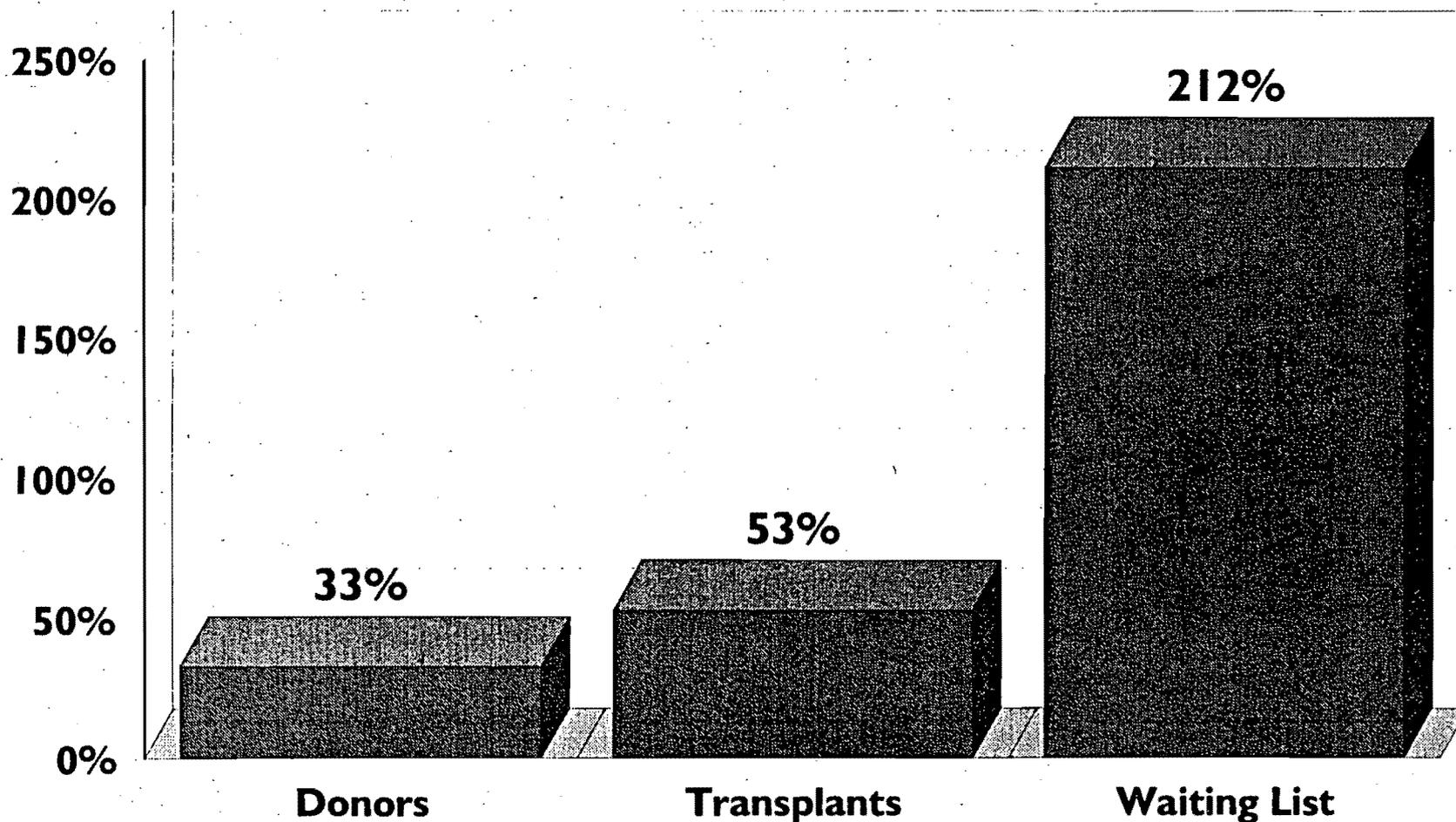
VI. Appropriations:

Congress will appropriate funds sufficient for the Board to carry out its functions for 2 years. No additional funds shall be appropriated for the operation of the OPTN. Within 2 years, The National Organ Transplant Governing Board shall develop private sources of funding to carry out its function as well as submit a plan to Congress to reimburse the federal government for funds appropriated for the initial 2-year operation of the Board.

Supply/Demand (1995 Data)

	All Organs	Livers
1. Waiting List	44,000	5,700
2. Number of Transplants		
cadaveric	16,825	3,900
TOTAL	20,100	3,925
3. Number of Organs Recovered		
cadaveric	19,700	4,330
TOTAL	22,990	4,370
4. Number of Donors		
cadaveric	5,360	4,325
TOTAL	8,540	4,360
5. Deaths Awaiting Transplants	3,550	800

Cadaveric Donors, Cadaveric Organ Transplants, and Waiting List at Year's End 1988-1996 (percent change)



Source: Donors from UNOS OPTN data as of 4/8/97, transplants from Scientific Registry data as of 4/8/97, "snapshot" of OPTN waiting list at end of each year.

DRAFT

Major Organ	Num. Pgms.: 1996	Num. Medicare Pgms.: 1997	Num. Tx.: 1996	Avg. Charge per Tx: 1996 (\$K)	Total Pgm. Revenues: 1996 (\$K)	Avg. Pgm. Revenues: 1996 (\$K)
Kidney	253	240	11,810	\$94	\$1,110,140	\$4,388
Liver	120	60	3,926	\$290	\$1,138,540	\$9,488
Pancreas	120	0	1,028	\$110	\$113,080	\$942
Heart	166	84	2,360	\$228	\$538,080	\$3,241
Lung	94	19	871	\$241	\$209,911	\$2,233
TOTAL PROGRAMS	753	403	21,991		\$3,109,751	
TOTAL HOSPITALS	281	253	21,991		\$3,109,751	\$11,067

Liver Transplant Program	1994 Volume	1995 Volume
UCLA Hospital Center, Los Angeles, CA	245	233
Presbyterian-University Hospital, Pittsburgh, PA	220	214
Mount Sinai Medical Center, New York, NY	175	209
Jackson Memorial Hospital, Miami, FL	116	193
Baylor University Medical Center, Dallas, TX	145	141
University of Chicago Medical Center, Chicago, IL	125	131
University of California, San Francisco, CA	106	97
University of Nebraska Medical Center, Omaha, NE	116	94
Rochester Methodist Hospital, Rochester, MN	76	91
University of Alabama Hospital, Birmingham, AL	63	82
Shands Teaching Hospital & Clinics, Gainesville, FL	36	81
University of Michigan Hospital, Ann Arbor, MI	79	78
TOTAL	1502	1644

State	City	No. Small (<12)	No. Medium (12-34)	No. Large (35<)	Total
AL	Birmingham	0	0	1	1
AK	None in State	0	0	0	0
AR	Phoenix	1	0	0	1
	Tucson	0	1	0	1
CA	Los Angeles area	1	2	2	5
	Sacramento	1	0	0	1
	San Diego area	0	2	0	2
	Bay area	0	0	3	3
CO	Denver	2	0	1	3
CT	Hartford	1	0	0	1
	New Haven	0	1	0	1
DC	Washington area	1	0	1	2
FL	Gainesville	0	0	1	1
	Miami	0	0	1	1
GA	Atlanta	1	0	1	2
HI	Honolulu	1	0	0	1
IL	Chicago	0	2	2	4
IN	Indianapolis	0	1	1	2
Total	17 Cities	9	9	14	32

[Livers]	Current	Partial Regional	Inpatient First	National
Percent Transplanted by Hospitalization:				
Inpatient	59%	73%	96%	97%
Outpatient	41%	27%	4%	3%
Share of Organs:				
Local	78%	44%	38%	20%
Regional	18%	28%	31%	6%
National	4%	28%	31%	74%
Number Transplants:				
Initial	10,992	10,998	10,451	10,231
Repeat	1,663	1,659	2,189	2,425
Total	12,655	12,657	12,640	12,656
Number on Waiting List at End:	11,534	11,788	12,729	13,050
One Year Survival Rate:	80%	81%	76%	73%
Deaths:				
Pre-transplant	3,704	3,599	3,168	2,963
Post-transplant	2,539	2,555	2,967	3,144
Total	6,243	6,154	6,135	6,107
Life-years:				
Pre-transplant	26,600	27,193	29,443	29,915
Post-transplant	24,712	24,840	22,759	21,765
Total	51,312	52,033	52,202	51,680

[Livers]	Current Policy	Partial Regional	Hospital First	National
Deaths:				
Pre-transplant	4,571	4,394	4,060	4,216
Post-transplant	2,468	2,487	2,734	2,527
Total	7,039	6,881	6,794	6,743
Life-years:				
Pre-transplant	15,093	17,837	19,580	18,683
Post-transplant	38,107	38,096	35,537	36,465
Total	51,200	53,933	55,117	55,148

OPTN Region	Current Liver Policy	Partial Regional
Region 1	102	123
Region 2	126	120
Region 3	23	70
Region 4	91	91
Region 5	121	113
Region 6	56	107
Region 7	118	113
Region 8	110	116
Region 9	119	99
Region 10	88	92
Region 11	70	76
Standard Deviation	32.24	17.93

Distribution of All Current Liver Transplant Programs

by 1995 Volume

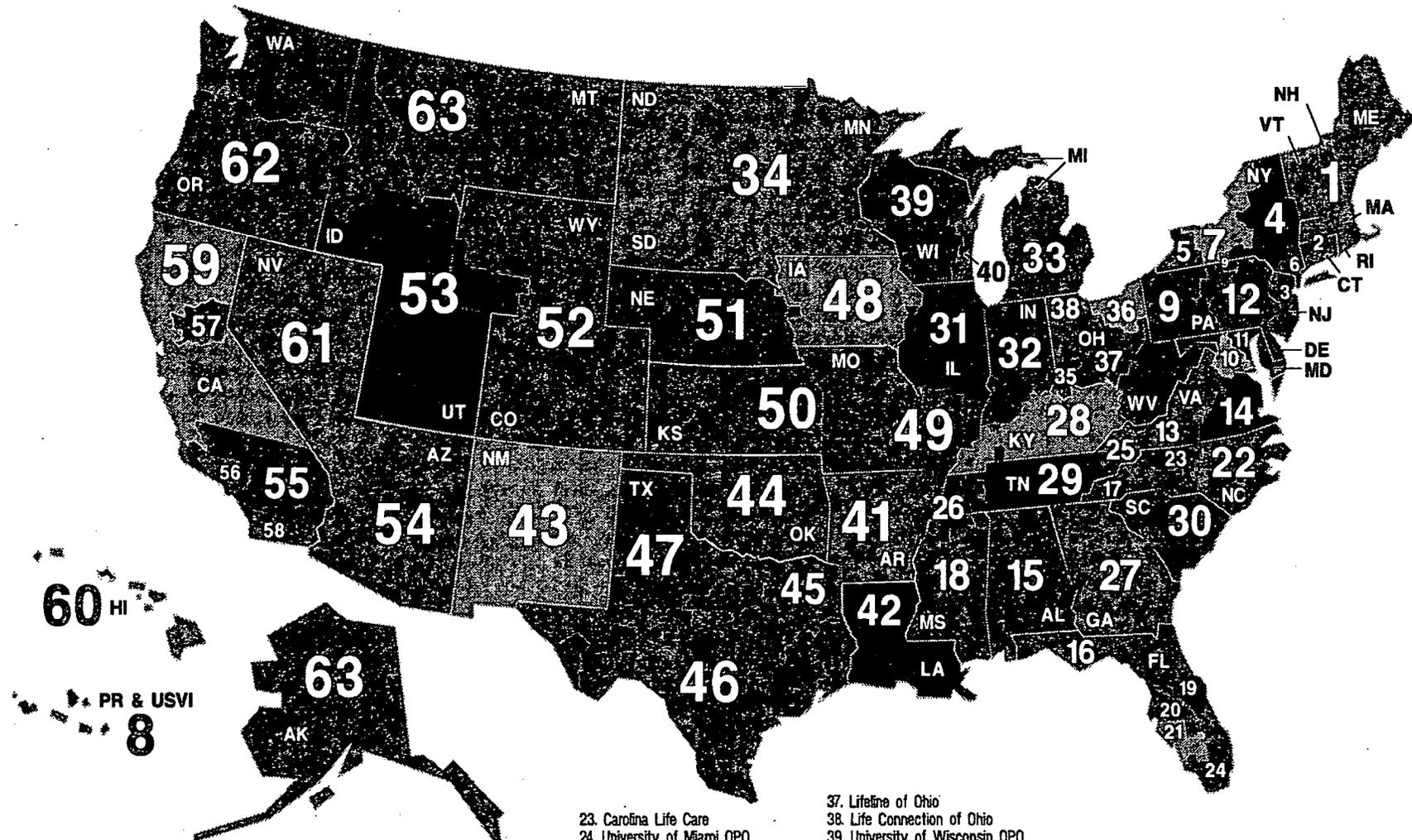


● 35 or more transplants

● Less than 35 transplants

UNOS

Organ Procurement Organization Service Areas, 1997



- 1. New England Organ Bank, Inc.
- 2. Northeast OPO and Tissue Bank
- 3. NJ Organ and Tissue Sharing Network
- 4. Center for Donation and Transplant
- 5. Upstate New York Transplant Services, Inc.
- 6. New York Regional Transplant Program
- 7. Univ. of Rochester Organ Procurement Program
- 8. Lifelink of Puerto Rico
- 9. Center for Organ Recovery and Education
- 10. Washington Regional Transplant Consortium
- 11. Transplant Resource Center of Maryland

- 12. Delaware Valley Transplant Program
- 13. Virginia Organ Procurement Agency
- 14. Life Net
- 15. Alabama Organ Center
- 16. The OPO at University of Florida
- 17. Life Share of the Carolinas
- 18. Mississippi Organ Recovery Agency, Inc.
- 19. TransLife
- 20. Lifelink of Florida
- 21. Lifelink of Southwest Florida
- 22. Carolina Organ Procurement Agency

- 23. Carolina Life Care
- 24. University of Miami OPO
- 25. Life Resources Donor Center
- 26. Mid-South Transplant Foundation
- 27. Lifelink of Georgia
- 28. Kentucky Organ Donor Affiliates
- 29. Tennessee Donor Services
- 30. SC Organ Procurement Agency
- 31. Regional Organ Bank of Illinois
- 32. Indiana OPO, Inc.
- 33. Organ Procurement Agency of MI
- 34. Upper Midwest OPO, Inc.
- 35. Ohio Valley Life Center
- 36. LifeBank

- 37. Lifeline of Ohio
- 38. Life Connection of Ohio
- 39. University of Wisconsin OPO
- 40. Wisconsin Donor Network
- 41. Arkansas Regional Organ Recovery Agency
- 42. Louisiana Organ Procurement Agency
- 43. New Mexico Donor Program
- 44. Oklahoma Organ Sharing Network, Inc.
- 45. Southwest Organ Bank
- 46. South Texas Organ Bank
- 47. Life Gift Organ Donation Center
- 48. Iowa State Organ Procurement Organization
- 49. Mid-America Transplant Association
- 50. Midwest Organ Bank
- 51. Nebraska Organ Retrieval System, Inc.

- 52. Colorado Organ Recovery Systems, Inc.
- 53. Intermountain Organ Recovery Systems
- 54. Donor Network of Arizona
- 55. Southern California Organ Procurement Center
- 56. Regional Organ Procurement Agency of Southern CA
- 57. Golden State Transplant Services
- 58. Organ and Tissue Acquisition Center of Southern CA
- 59. California Transplant Donor Network
- 60. Organ Donor Center of Hawaii
- 61. Nevada Donor Network
- 62. Pacific Northwest Transplant Bank
- 63. LifeCenter Northwest

THE WHITE HOUSE
WASHINGTON

Date 11/2/99

To: CHRIS JENNINGS

From: The Staff Secretary

ANY COMMENT?

Organ Allocation File



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

OCT 27 1999

MEMORANDUM FOR THE PRESIDENT

As you know, the Department of Health and Human Services has been working for a number of years toward improving the Nation's system of organ procurement and transplantation. Our goal is to make the system operate for the greatest possible benefit of patients. We believe improvements in the organ transplant system could result in saving hundreds more lives each year.

Toward the goal of saving more lives, we have moved in two areas. With the Vice President's leadership, we have undertaken a National Initiative to increase organ donation. This effort has produced successful results in its first year. At the same time, HHS developed regulations to carry out the purposes of the National Organ Transplant Act of 1984. These provisions, developed over a period of years with extensive opportunities for comment, were published as a Final Rule on April 2, 1998.

Our Final Rule was supported by patients' groups and many prominent transplant centers and professionals, but was opposed by the HHS contractor which operates the Organ Procurement and Transplantation Network (OPTN) and by others in the transplant community. Last Fall, Congress imposed a one-year moratorium on implementation of the Final Rule, and mandated that a study of the issue be carried out by the National Academy of Science's Institute of Medicine (IOM). Congress also asked for further consultation between HHS and the transplant community. Both of these actions have been completed.

The IOM published its study in July. Its findings strongly validated the concerns and the approach of the HHS Final Rule. In particular, the study reinforced the need for Federal oversight of the Nation's organ procurement and transplantation system -- not to impose government in medical decision-making, but to ensure that the policies of the OPTN were operating fairly and effectively in the public interest. Throughout this year, HHS also continued meeting with the various elements of the transplant community, listening to concerns about the Final Rule and identifying common goals.

On October 20, HHS published amendments to the Final Rule which reflect the findings of the IOM report as well as our discussions with the transplant community. These amendments especially benefit from the input provided by the IOM, and they represent improvements in the

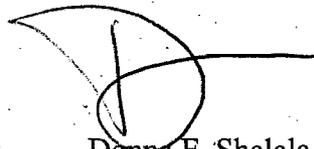
Final Rule. But at the same time, we have preserved the core features of our Final Rule, which are the foundation for improving our system for patients. In particular, this means using standard medical criteria, developed by transplant professionals themselves, to decide which patients will receive organs. This is the only way to ensure that organs will reach patients who need them most.

Opponents of our Final Rule are once again seeking to use the Appropriations process to impose a renewed moratorium on the Final Rule. The Administration is on record as strongly opposing any new moratorium. I want to urge that we remain strong in defending our current position and insist that the regulation go forward as scheduled. Our approach has been validated by the IOM study that Congress ordered, we have listened to the concerns of all elements in the organ transplant community, and we must remain committed to an organ transplant system that saves more lives by serving patients in the fairest and most medically effective way possible.

In addition, both Congress and the Executive Branch should be concerned about the integrity of Federal spending for transplants. Medicare and Medicaid alone pay for more than half of transplant costs in the United States. However, without the Final Rule to define the Federal role in our transplant system, the government has little useable authority to assure that these Federal dollars are being used in a fair and effective manner.

Our goal is to work cooperatively with the transplant community to ensure the best possible transplant system for Americans. We have been careful not to inject government into decisions which must be left to medical professionals. Instead, we have designed a carefully balanced approach in which the Federal Government can carry out the oversight role which the IOM so clearly reaffirmed.

For these reasons, I would urge you to reject any actions by Congress that would further delay implementation of the Final Rule.

A handwritten signature in black ink, appearing to be 'D. Shalala', written over a circular stamp or mark.

Donna E. Shalala

Attachments

Wash. Post; 10-23-99

An End to Organ Games?

THE FIGHT between the federal government and local organ transplant centers over how better to allocate scarce organs has been a strikingly unsavory application of territorial politics to an area where politics should play no role. This week the Department of Health and Human Services (HHS) published a final regulation—to go into effect in 30 days—intended to make organ distribution more equitable. The idea is to even out disparities among the many geographic areas served by the nation's 272 transplant centers, most of which grew up in an era when "harvested" organs needed, for technical reasons, to be used close to home. The varying populations of these regions mean uneven distribution, which, given the shortage of organs, spells death for some 4,000 patients a year for whom an organ cannot be found in time.

Enter HHS, which last year issued a draft regulation calling for the network's contractor, United Network for Organ Sharing, to come up with more equitable criteria based on medical, rather than geographical, status. The organ transplant network, though, fiercely opposed the regulation and persuaded Congress to delay its implementation a year. The network fears the changes would force local transplant centers to close, which in turn would dissuade families from donating loved ones' organs; it also warned of organ wastage

because of failed procedures if the sickest patients were invariably transplanted first.

Behind these concerns—for which a congressionally mandated report from the National Academy of Sciences' Institute of Medicine found no evidence—is the fear that local centers would close, eliminating the substantial income source they represent for the hospitals that house them. That may explain the otherwise remarkable fact that 10 states responded to the proposed rule by passing laws making it more difficult to send organs out of state. The Institute of Medicine report even cites cases where grieving families willing to donate were urged to sign contracts requiring that organs go only to in-state recipients.

In fact, the report's researchers found no evidence that families care whether organs are used nearby; on the contrary, surveys showed they cared most whether the organs would be fairly used. The report recommends that geographical regions be made larger but that any new system make use of existing transplant networks rather than closing them down, a goal HHS Secretary Donna Shalala says could be achieved under the rule. Opponents of the reforms could still hobble and delay the regulation further as part of the budget appropriation for HHS. Such an action would be an extension of a cynical battle that costs patients' lives as it drags on.

MONDAY, OCTOBER 25, 1999

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Senior Vice President

Ensuring a healthy system

By keeping the details open to doctors' suggestions, feds may produce a better organ donation network

The Clinton administration continues to push for a more rational system of allocating donated organs. That's good for sick people.

But the push leaves a lot of room for input from hospitals and doctors involved in transplant surgery. That's good for all concerned.

Whether the United Network for Organ Sharing, the hospital organization that set up the current system of allocating transplants, can recognize the common good remains to be seen. Thus far, UNOS has been much too intent on defending its methods to acknowledge that patients might be better served by a few changes.

Donna Shalala, secretary of Health and Human Services, has expressed a willingness to lay down the law if UNOS balks at doing its work the way its employer, the federal government, wants it done. But Shalala cleverly has stopped well short of dictating precisely what UNOS must do.

Instead, her department has set forth broad administrative requirements and left the details for the medical professionals at UNOS to decide.

As a result, comments like those of UNOS board member Ronald Ferguson of Ohio State University, couldn't possibly ring more hollow. "I support keeping medical decisions about transplant in the hands of the doctors that are caring for the patients. I oppose the intrusion of the government into the process," Ferguson says in a letter he has been asking his patients to mimic, sign and send to Congress (an actively intrusive arm of the government, last time we checked).

Good for you, Dr. Ferguson. Your argument in favor of keeping doctors in charge of curing patients is right in line with what Secretary Shalala wants, loath though you may be to admit it.

She is asking only that the criteria hospitals use to determine a patient's place on a transplant waiting list be standardized around the country, and that any donated organ be made available to the patient in most urgent need in a region larger than a single state. Further, HHS wants UNOS to establish performance measures so transplant centers' work can be evaluated.

Those broad requirements are fair, sensible and in line with advances in organ transplantation, preservation and transportation. The details of how to meet those requirements are the medical professionals' to decide, which is as it should be.

Unfortunately, the medical professionals at UNOS became used to lax HHS oversight over the years, and rare indeed is the hospital or doctor eager for performance evaluations. So it is no surprise that this government contractor has enlisted allies in Congress to help it become a law unto itself. That should not be allowed to happen.

The small burdens the Clinton administration is asking UNOS to take on hold great promise for improving the treatment of patients. But if the medical professionals best suited to do the job fail to do it, the government will have to step in and do its imperfect best.

July 26, 1999

Improving Access to Organs

Forum

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For more than a year the Clinton Administration has been trying to improve the way human organs donated for transplants are distributed to patients around the country. But Congress, responding to intense opposition from transplant centers, has blocked the use of new Federal regulations that aim to broaden organ sharing across arbitrary local lines. A new report by the Institute of Medicine, a branch of the National Academy of Sciences, confirms that changes are needed to make the system more fair and effective.

The current system directs most organs to be used in the local area where they were donated. That can create unfair situations where patients who are less ill may get transplants while more severely ill individuals who happen to live outside the local organ procurement area are made to wait. This has become an increasingly important public health issue, since about 4,000 Americans die each year while waiting for transplants.

The Department of Health and Human Services tried to address the problem by issuing new regulations last year. These direct the United Network for Organ Sharing, a private organization that coordinates organ distribution nationally, to design a new allocation system that puts more emphasis on medical criteria and leaves less to geography. But Congress delayed that directive from going into effect until this October. The network insisted that the rules would force small transplant centers to close and discourage organ donations if donors knew organs would go outside their community.

The Institute of Medicine report, commissioned by Congress, found those fears to be overblown. The report, which focused on liver transplants, said waiting periods for the very sickest patients were actually comparable across the nation. But there were differences in waiting times for patients who were less ill. The report recommends improving distribution by requiring that organs be shared across

wider regions based on population, so long as the regions are not so geographically large as to pose problems in transporting the organs.

The report also affirmed the need for more active Federal oversight and greater scientific review of allocation principles. These recommendations are consistent with the Administration's approach. The transplant community should drop its resistance to Federal regulations that could make the system more equitable for patients everywhere.

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THE LANCET

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Changing the US transplant system

In the USA, where you live can determine whether or not you receive an organ transplant. That is because the US organ allocation system is broken up into 11 regions and operates a "locals first" policy in which organs are first offered to patients in the area where the organs were obtained, then to patients in the surrounding region, and finally to patients in the rest of the nation. As a result, a patient living in one part of the country may receive a transplant before another patient with greater medical need living in another part of the country.

To try to reduce such geographical disparities, US Secretary of Health and Human Services, Donna Shalala, has proposed new regulations that will require the national Organ Procurement and Transplantation Network (OPTN), a private sector system of organ procurement organisations and transplant centres established by the 1984 National Organ Transplant Act, to revise its allocation policies so that eligible patients are not denied a transplant because of where they live.

Precisely how the OPTN is to attain this goal is left to the network to work out, but the policies must satisfy three performance goals. They must establish standardised criteria for determining which patients are medically eligible to be put on transplant waiting lists and for determining the medical status of patients, so that the medical needs of different patients can be compared; and they must set up allocation protocols that will reduce the influence of geographical factors so that organs will first go to those with the highest medical urgency. In pursuit of these goals, however, the regulations do not require the OPTN to adopt policies which, because they are impractical or are contrary to sound medical judgment, lead to futile transplants and organ wastage.

On the face of it, it is hard to see what is objectionable about Shalala's proposal, but the response of the United Network of Organ Sharing (UNOS), the DHHS contractor that operates OPTN, has been furious. In a letter sent to every US Senator last spring, the outgoing president of UNOS, L. G. Hunsicker, described the regulations as a "federalization of the current system which takes away control of the transplant system from doctors

and patients in almost 300 transplant centers and hands it over to Federal regulators" and forces doctors to give livers "to the very sickest patients", who are likely to require second or third transplants and thus use organs that could have gone to save other patients. Hunsicker predicts that the regulations will make it more difficult for most patients to receive a transplant because organs will be shunted towards a few large transplant centres with the longest waiting lists and the sickest patients.

But it is hard to see how the regulations amount to a "federalization" of the US transplant system, when they merely set performance goals and allow OPTN to develop the policies. The regulations also do not require that transplants be given to the "very sickest" patients but rather that preference be given to those who are "very ill but who, in the judgment of their physicians, have a reasonable likelihood of post-transplant survival" over those who are less medically urgent. Finally, it is hard to predict, before OPTN has formulated the final policies, what impact the regulations will have on smaller transplant centres. However, it can be argued that since where organs will go will depend on the needs of patients and not the size of the transplant centre smaller programmes could fare well under the new rules.

But what is clear is that the rhetoric adopted by UNOS and other opponents of the proposal is not helpful and has already caused mischief. Two states have passed legislation that gives state residents priority for organs donated within those states. Several other states are considering similar laws, which, if they survive court challenge, will further fragment the US organ allocation system.

The new regulations proposed by Secretary Shalala seem to give the network sufficient leeway to move closer to the desired goal without requiring it to adopt policies that will waste organs or force doctors to perform futile transplants. UNOS would better serve the transplant community if it abandoned its stance and began working with DHHS to draw up allocation policies that are practical and fair.

The Lancet

USA TODAY

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Top 10 sleeper: Grass-roots marketing vaulted biblical 'Omega Code' into a weekend box office hit.

Tuesday, October 19, 1999

'Fairer' transplant rules set

HHS policies would reduce inequities in organ cases

By Robert Davis
USA TODAY

Years of debate over how organs are allocated for transplants ended Monday with government rules that will require strict accountability from doctors and establish more uniform criteria for deciding which patients get organs.

The Department of Health and Human Services, which has been concerned about unfairness in patient selection and large regional variations in availability of organs, is requiring a new set of "core policies" that will change the medical community's handling of transplant cases.

The policies are intended to lessen the importance of waiting lists, force hospitals to share more information about more patients and minimize inequities that can lead to heart-breaking medical choices.

Government officials have been concerned that doctors sometimes pick their own relatively healthy patients over very sick patients in a hospital across town or in another state.

The rules are intended to ensure more protection for sicker patients and establish a series of criteria that treat all patients by one set of rules, including survivability.

"We think that this is going to improve (patient) survival overall," said Claude Earl Fox, administrator of the Health Resources and Services Administration.

"We think it is going to be a fairer system."

The transplant community, which has expressed concern about loss of medical independence, reacted cautiously.

"We absolutely believe (Secretary of Human Services Donna Shalala) should exercise oversight, but we do not believe the secretary should be making medical decisions," said a statement from Ronald Busuttil, president of the American Society of Transplant Surgeons.

The private group that runs the transplant system, the United Network for Organ Sharing (UNOS), said it was still reviewing the rules, which take effect in about 30 days.

The rules call for UNOS to establish policies that would:

- ▶ Establish the same basic criteria to decide which patients get transplants and when.

- ▶ Expand organ-sharing regions to ensure that organs reach patients who need them most. A recent report found that the wait for organs was 46 days in Iowa but 72 days in western Pennsylvania.

- ▶ Release information on the public to allow physicians and patients to identify the most



Leave, and leave now. Donna Shalala takes on a rogue contractor, so far to no avail.

The Organ King

An outfit with life-and-death power over patients waiting for transplants has evolved into a heavy-handed private fiefdom.

BY BRIGID MCMENAMIN

EVER SINCE FORBES EXPOSED THE federal monopoly that's chilling the supply of transplantable organs and letting Americans who need them die needlessly (FORBES, Mar. 11, 1996), Health & Human Services Secretary Donna Shalala has been trying to challenge the way United Network for Organ Sharing operates.

But the Richmond, Va.-based cartel will have none of it. Using a heavy-handed mix of litigation, lobbying and bullying of its opponents, UNOS has solidified its position as the federal contractor in charge of deciding which people get new kidneys, livers or hearts.

Under the UNOS system, most organs are shared only within 62 regional territories. A potential recipient in, say, New York, where donations are low, can expect to wait months for an organ to show up, even though there may be so many donors across the river in New Jersey that New Jersey patients are getting transplants after short waits or when they are far from desperate.

Though UNOS has begun to relax the locals-first policy, still, last year 4,855 Americans died while waiting for transplants. (This doesn't even count

people pulled off the list after they became too sick to handle a transplant.) It is a matter of debate how much lower the number of deaths would be if the system for obtaining and allocating organs were more rational. But Consad, a research outfit in Pittsburgh, estimates that at least 1,000 people die needlessly each year.

When Shalala urged that organs be shared over wider regions, UNOS Executive Director Walter K. Graham refused. He decreed, in a memo to his member hospitals and organ banks, that UNOS doesn't have to take direction from the federal government on this point.

UNOS' main source of funding is the \$375 registration fee potential organ recipients must pay to get on the waiting list. That amounts to some \$13 million a year, money that is supposed to be spent mostly to match organs with suitable recipients. In reality, at best half of the money goes to that.

What about the rest? Graham and his 40 board members spend some \$1 million each year on jetting around and on meetings and confer-

ences. A new \$7 million headquarters building is planned. In 1997, some \$1.6 million went for items network officials refuse to explain. "They really never tell you what they're spending money on," says veteran board member John Fung, a liver surgeon at the University of Pittsburgh.

When Shalala tried to exert more control over the rising registration fees, Graham challenged her in a proceeding before the U.S. General Accounting Office, claiming she had no right even to know how he spent the fees. The suit was settled; Shalala backed down.

Why not simply bring in another contractor to ration organs? Good luck. The congressional committee in charge of such matters is headed by Representative Thomas Bliley, from UNOS' home city of Richmond. His cousin Paul S. Bliley is a law partner of UNOS lawyer Malcolm E. (Dick) Ritsch. Last fall, then-Louisiana Congressman Robert Livingston, whose home state includes eight profitable transplant centers, pushed through a bill halting further attempts by Shalala to control the contractor.

After the Senate rejected this moratorium, Livingston got it tacked onto another bill behind closed doors by threatening to hold up funding for the International Monetary Fund. The moratorium ends Oct. 21. But UNOS has already had Wisconsin Congress-



UNOS' hometown congressman, Thomas Bliley, heads up the committee that oversees transplant matters.

PHOTO: LAUREN ABERNETHY (TOP); ASSOCIATED PRESS / TERRY MALLOY (BOTTOM)

man David Obey tack another one-year extension onto a bill that was set to go to the full House for a vote in October. His state's four transplant centers stand to lose organs if UNOS loses its grip.

Craig Howe, executive director of the National Marrow Donor Program, recently expressed interest in having his organization bid on the organ contract. After UNOS found out he was interested, his board members, who include 14 physicians, axed him. Although some powerful and prominent surgeons like Fung are an exception, most doctors involved in the business fear offending UNOS lest their organ supply be affected.

In another instance FORBES is aware of, UNOS threatened to retaliate against an outfit it perceived as a rival bidder for the organ allocation job.

Tax-exempt groups like UNOS are supposed to make their financial state-

ments available for public perusal. But UNOS hides significant activity behind two little-known affiliates that aren't required to disclose anything.

The first is the UNOS Foundation, a six-year-old shadow organization run by UNOS staffers. Spokesman Robert

UNOS milks desperate patients to subsidize a stealth for-profit firm.

Spieldenner claims the foundation doesn't have to file tax returns because it brings in less than \$25,000 a year. The UNOS Foundation owns something called the Transplant Informatics Institute, a for-profit company run by organ network staffers. Transplant Informatics is so secret that even some UNOS board members are unaware that it exists.

What does the institute do? The government thinks it markets UNOS-developed software to organ network members. In an audit looking into the use of registration fees for lobbying, the Office of the Inspector General got just that impression. What the institute really does is analyze and sell organ network data to profit-making companies like Fujisawa, the Japanese firm that sells drugs for transplant patients. When the institute has not been able to cover its costs with such sales, UNOS has used

its registration fee income to make up the difference. Prospective organ recipients are therefore effectively funding this hidden business.

You'd think someone on UNOS' board would scream bloody murder about all this. After all, the 40-person board is almost half doctors, dedicated to saving lives. But the directors have little idea what's going on. "The board

is kind of in the dark," sighs patient advocate Charles Fiske, a former board member.

"We received an annual financial report and pretty much accepted it as written," says University of Oklahoma transplant doctor Larry R. Pennington, a board member from 1996 to 1998. They really don't know how to interpret the data. "All I'm familiar with is hospital sort of activity," admits transplant physician William Harmon.

Realizing that UNOS is out of control, Shalala has put out feelers for a replacement. "I hope we have some bidders this time," sighs Claude Fox, a pediatrician who, as administrator of the Health Resources & Services Administration, oversees transplants for Shalala. The only prospect so far is Santa Monica-based Rand.

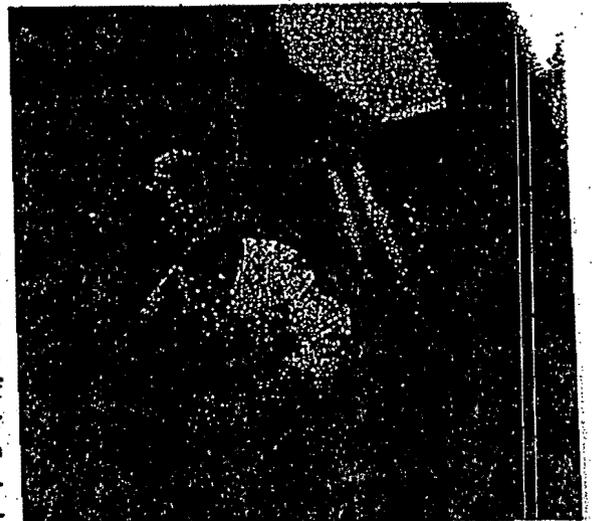
Determined to see that Rand does not walk off with the contract, UNOS lobbyists are pushing for a law that

would insure that Graham's group will keep the contract forever. Last month Bliley's committee held hearings on a bill which would require the organ rationing contractor to have experience, something no group but UNOS has. It would also allow UNOS' members to vote on the choice.

"Anything that gives them more of a stranglehold isn't in the public interest," says Fox. "It's like giving the EPA to some land-fill company," says Dr. Fung.

It would be nice if UNOS didn't have a lock on this business. Better still if the federal government stepped out of the process altogether and let doctors come up with creative ways to increase the supply of organs. (How about giving

people who sign up as potential donors when they are young some priority in getting organs when they are older?) Once there are enough hearts and livers to go around, there won't be unaccountable arbiters holding sway over our lives.



Disillusioned patient advocate Charles Fiske.