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D01, note	Phil Caplan to POTUS re: Liver Transplant Issue (1 page)	2/12/97	P5

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FOLDER TITLE:

Health Care-Organ Transplants [1]

rs83

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

Executive Secretariat

FACSIMILE

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FROM: LAVARNE BURTON

FAX NUMBER: _____
OFFICE NUMBER: 690-5627



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

OCT 5 1998

MEMORANDUM TO THE HONORABLE ERSKINE BOWLES

As you know, the Department of Health and Human Services issued a final regulation on April 2 to bring about improvements in the Nation's organ transplantation system. In particular, this regulation is aimed at ensuring that allocation of scarce organs would be based on common medical criteria, medical need and medical judgment, not accidents of geography. Under the current system, less ill patients may receive transplants while more severely ill patients, perhaps only a few miles away, die. Organs should be allocated to patients who are medically judged to need them most, no matter where they live, or at which transplant hospital a patient chooses to list.

Opponents of our regulation, led by transplant centers in Louisiana and Wisconsin, worked with Chairman Livingston and Congressman Obey earlier this year to include in the supplemental appropriations bill language to delay implementation of the rule until Oct. 1; and subsequently, in the House FY 1999 Labor/HHS bill, to delay the rule by another year. Senator Specter, the chairman of our Senate appropriations subcommittee, plans to fight with us against the House rider. This could be one of the most contentious policy rider issues during negotiations on the omnibus appropriations bill.

I want to urge that the Administration very strongly defend our current position in this matter. The reason for doing this is in large part, of course, because of its positive impact on patients. The regulation fundamentally shifts the focus of organ allocation policy from transplant center benefit to patient benefit.

In addition, however, I believe the most fundamental question of Executive Branch responsibility is at stake. The Federal Government, on behalf of Medicare and Medicaid beneficiaries as well as veterans, is the Nation's largest payer for transplant services. Medicare and Medicaid alone pay for more than half the transplant surgeries in the United States. However, organ allocation policies, which ultimately determine who shall receive organs, are set by an HHS contractor, the United Network for Organ Sharing (UNOS), not by HHS itself. Insofar as Congress wants independent medical guidance, UNOS' policy-making role is desirable, and we at HHS respect it. At the same time, however, it seems clear that Congress does not intend for the Federal Government to be without any oversight role in the determination of organ allocation policy, since without federal oversight, the expenditure of these substantial funds is essentially steered by those receiving the funds, and patient interests are far under-represented.

These are the issues at stake in ensuring that Congress allows our regulation to be implemented: the core authority of the government over policies that dictate substantial Federal spending, in addition to the well-being of the patients for whose care we are paying. In our view,

Page 2 - The Honorable Eyrskine Bowles

the law clearly established the national transplant system as one that is intended to benefit patients by treating donated organs as a public trust. Yet over the years, UNOS allocation policies have increasingly strayed toward choices that are made to benefit the interests of transplant centers rather than benefiting patients with greatest medical need. UNOS, which de facto represents the interests of the majority of transplant centers, maintains that it believes Congress meant HHS to have no oversight role in organ allocation policy. We maintain that the law clearly intends for the Secretary of HHS to have final approval authority for policies that are appropriately devised by the transplant community.

Let me make clear that in our regulation, the Department specifically chose not to mandate any specific organ allocation system, but rather to set broad performance goals for the transplant community. This entirely respects the appropriate UNOS role. Under the goals set out in the regulation, the private sector transplantation network is to develop medically sound allocation policies to improve fairness and establish uniform medical criteria. As of the date the final regulation takes effect, the transplantation network will have 60 days to develop a proposed allocation policy for livers, and one year to develop proposed policies for other organs. But no new system of organ allocation goes into effect until these proposals developed by the network are published for public comment, considered by the network and accepted by HHS. We are making the same point in litigation filed in Louisiana. Although a District Court judge has temporarily stayed the effective date of the regulation, the Justice Department is preparing to immediately appeal.

The work done by HHS on this regulation is based on the law passed by Congress to ensure fairness in our organ transplant system (the National Organ Transplant Act, for which Vice President Gore had a substantial guiding role.) HHS published its proposed rule in 1994, and three extensive comment periods have been provided, including three days of special hearings. Congress has also held several hearings on this subject. This regulation has had exceptionally broad consideration and comment.

I cannot overemphasize the time, thought, and good faith that has gone into the development of this regulation. Because we recognize that core questions of Executive authority are involved, we have been scrupulous in honing this regulation to one that is responsive to the governing statute, places the focus on patient benefit, and protects the right of the Federal Government to approve policies that direct its spending.

For these reasons, I would urge you to reject any actions by Congress to delay implementation of this regulation. Such a delay would compromise patient well-being and the authority of the Federal Government to approve policies that determine substantial expenditure of tax dollars.



Donna E. Shalala

(from Fredkin)
cc: JRM, Chris, EK
+ return
-BSR

Barry Reed
label design
[Signature]

Proposal: Federal Initiative in Transplantation Research

Overview

- In order to address the multiple problems posed by increasing incidence of diabetes and many other autoimmune diseases, the federal government would spearhead a collaborative, multi-disciplinary initiative in transplantation-related science. The ultimate goal would be to cure these diseases, thereby alleviating human suffering and reducing health care costs. While the primary focus would be on islet cell transplant (diabetes), many of the research projects would also apply to and benefit other serious diseases as well (e.g., rheumatoid arthritis, lupus, and multiple sclerosis).
- Through new National Institutes of Health (NIH) dollars and re-direction of existing funds, \$100 million could be provided for this initiative as one of the NIH Director's "Special Areas of Emphasis." An alternative approach would be a multi-departmental collaboration involving NIH, Department of Defense, Department of Commerce, NASA, and the Department of Veterans Affairs. The President and Vice President could make an announcement of this effort at the White House, ideally in November during National Diabetes Month, with bipartisan representation from Congress, the diabetes community, and other interested parties.

Burden of Diabetes

- Diabetes is a major public health problem affecting approximately 16 million Americans from all walks of life. An estimated 650,000 new cases of diabetes will be diagnosed this year alone. According to the NIH, the direct and indirect costs of diabetes exceed \$137 billion per year, making it the single, costliest, chronic disease in the U.S. It is estimated that people with diabetes account for approximately 25 percent of Medicare expenditures.
- Diabetes reduces life expectancy by up to 30 percent. This year alone, diabetes and its complications will contribute to the deaths of over 170,000 Americans. It is a leading cause of blindness, amputations, kidney failure, and cardiovascular disease, and disproportionately affects African American, Hispanics, and Native Americans.

Proposal: Federal Initiative In Transplantation Research

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17 July 1997

Scientific Rationale

There have been significant advances in our understanding of how the immune system behaves in rejecting a "foreign" organ or tissue. An upcoming NIH-sponsored conference on the state of diabetes research will likely highlight many of these advances. The challenge in this area now is to translate the knowledge gained from basic research to clinical application. The goal of this research would be to develop treatment which would "fool" the immune system into accepting an organ or tissue without causing dangerous side effects. A significant breakthrough in this area would result in the ability to:

- transplant islet cells in people with both Type 1 and Type 2 diabetes (and other diseases) without use of toxic immunosuppression drugs; and
- significantly extend the life of transplanted organs, and thereby improve the outcomes of other solid organ transplants.

Finally, almost every single institute at the NIH, as well as research programs across other agencies of the federal government, has an interest in the clinical application of transplantation tolerance. A coordinated approach, which provides funds for the "translational" research necessary to move knowledge from the research lab to the patient's bedside, and which puts into place a system for monitoring and expediting new discoveries, would have an enormous impact on American science and medicine.

Other Complementary Federal Efforts

- Secretary of HHS Donna Shalala is planning new initiatives in the area of organ donation and allocation that are designed to address the critical shortage of organs. To the extent that new breakthroughs in transplantation science can extend the life of transplanted organs, the proposed research initiative would support these important efforts on organ donation and allocation.
- Similarly, the Institute of Medicine (IOM, part of the National Academy of Sciences) is holding a conference this week on the state of transplantation. This IOM-headed effort will focus on: development of strategies for increasing organ donations; ways to improve efficient and ethical uses of existing transplant materials; and identification of scientific and technical advances in cell and tissue transplants.

Proposal: Federal Initiative in Transplantation Research

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17 July 1997

- Other complementary efforts include NASA's support of cell engineering, cell growth and differentiation, and islet cell transplantation; and the Commerce Department's tissue engineering initiative with private industry which seeks, among other things, to stimulate islet cell transplantation technology.

H-C Organ

UAB THE UNIVERSITY OF ALABAMA AT BIRMINGHAM

Office of the President
Governmental Relations

May 2, 1997

Mr. Bruce Reed
Assistant to the President
for Domestic Policy
The White House
Washington, DC 20500

Dear Mr. Reed:

We greatly appreciated the opportunity April 14th to meet with you and express our views on organ transplantation and liver allocation. Later that afternoon, we met and discussed these same matters with staff from the Congressional offices shown below. It seemed to us that both meetings involved two basic questions: first, how should the National Organ Transplant Act organize the process for making decisions about organ transplantation and, second, should DHHS use its rulemaking authority to make significant changes in the current method of allocating and distributing livers for transplantation.

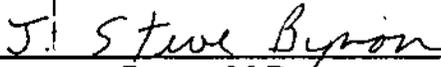
The first question relates to process, and, as we explained, we and the great majority of our colleagues across the country are strongly supportive of the role of UNOS. It is broadly representative and its committee structure affords ample opportunity for all points of view on any issue to be heard. We reject categorically any implication that smaller, more numerous, transplant centers ignore substance and vote only in their self interest. In our experience, UNOS has always given the issues before it serious and deliberative consideration.

At the same time, we understand that DHHS should have a role in ensuring that UNOS decisions are accountable in an overall sense to the broader public interest. In this regard, we think it vitally important that there should be a clear distinction made between kinds of determinations made through UNOS by those directly involved in transplantation - patients and their families, OPO staff, transplant centers and physicians - and the goals and functions of a policy-level review on behalf of the general public interest. Perhaps the way that NSF and NIH use expert panels to evaluate the scientific merit of competitive grant applications, but employ appointed groups, such as the National Science Board, to establish evaluation criteria and identify areas of national priority, might be adapted to this situation. What in our view must not happen, however, is for the Department to duplicate the UNOS process or serve as an appeal mechanism for substantive UNOS decisions. We believe that this would be a terrible mistake.

Page Two
Letter to Mr. Bruce Reed
May 2, 1997

With respect to liver allocation, we believe strongly that the current methodology serves those patients in need of transplantation and the larger national interest well. Under the current system, there has been an expansion of the number of centers providing high quality liver transplantation services, the number of such transplants has increased steadily and the access to liver transplantation has greatly improved, particularly for patients with limited financial resources. Further, we are convinced that there is no alternative allocation method that offers a distinct improvement for patients. We hope that during our discussion we gave you a sense of how truly complex this subject is. As long as there is a shortage of available organs, there will be no ideal solution, but in our view, local primacy operates as a reasonable balance among several goals and results in the best overall outcome for patients and their families.

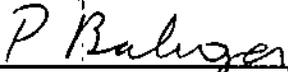
Sincerely,



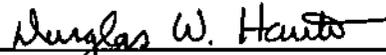
J. Stevenson Bynon, M.D.
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C. Wright Pinson M.D.
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Prabhakar Baliga, M.D.
Medical Univ. of South Carolina



Douglas W. Hanto, M.D., Ph.D.
Univ. of Cincinnati Med. Ctr.

c: The Honorable Spencer Bachus
The Honorable Mike DeWine
The Honorable Bill Frist
The Honorable John Glenn
The Honorable Ernest Hollings
The Honorable Jeff Sessions
The Honorable Richard Shelby

**NATIONAL TRANSPLANT ACTION COMMITTEE
70 SEWALL AVE
BROOKLINE, MA 02324
(617) 566-3430**

April 14, 1997

Mr. Bruce Reed
Deputy Asst. to the President
for Domestic Policy
The White House
Washington, DC 20500

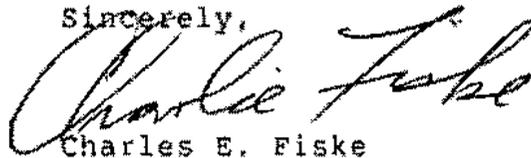
Dear Bruce,

Thanks for meeting with me on Wednesday the 9th regarding some of the ongoing issues with the the National Transplant Act. Your long involvement with this issue through then Congressman Gore's office gives you great insight to the strides made in transplantation since the early 80's. Transplant programs have increased and many lives have been saved.

It's my hope that through the intervention of your office, public policy can be developed in a way that reflects the best interest of all citizens no matter where they live. Part of the difficulty rests with the blurred relationship between the transplant network(OPTN) and the contractor(UNOS). Currently, the contractor functions as the network so that full discussion of public policy may not be as objective as was originally intended by Transplant Act. Flawed public policy is only complicated by the continued shortage of organs. Unless public policy reflects goodwill from all interested parties especially patients, then specific issues such as allocation will continue to demand great amounts of time.

Again, I thank you for taking the time to meet.

Sincerely,



Charles E. Fiske

PS. Enclosed is a copy of NTAC suggested changes for reauthorization to the Transplant Act. They've already been submitted to the Department.

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.

David M. Metter

501 LINCOLNCLIFF ROAD * PITTSBURGH, PENNSYLVANIA 15221

April 15, 1997

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Gentlemen:

On behalf of the representatives of the University of Pittsburgh Medical Center, Mr. Charles Fiske of the Family Inn located in Brookline, Massachusetts, and myself, I wish to thank each of you for taking the time from your busy schedules to visit with us on the issue of allocation of livers donated for transplantation. It was obvious from your questions and comments that you were already well informed regarding many of the issues and arguments involved in this important public policy decision. However, we wanted to provide you with further comments and clarification with respect to three of the issues discussed in our meeting and to bring one additional item of interest to your attention.

First, Mr. Jennings is correct that a significant increase in organ donation, for all organs not just livers, would correct many of the problems and ease much of the anxiety in the transplantation community. Increasing donation is a goal of most of the professionals and institutions involved with organ transplantation. Many procurement organizations and transplant centers across the country have started innovative new programs to increase donor awareness, have pursued state legislative efforts to increase donation rates, and have committed significant time and money to donor education programs. A significant increase in organ donation, however, is a long-term, rather than an immediate solution to the current problem of patients dying while waiting for a liver transplant. It has become obvious from the

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experiences over the last ten years that it will take a prolonged and enhanced effort at education, trust building and, in some cases, cultural modification before we can hope to see any significant increase in donation rates. In the interim, the Department and this Administration can, with the stroke of a pen, implement programs which will save the lives of nearly 300 patients over the next three years. We are not in an "either/or" situation; rather, there is a "both/and" response to this problem. The Department can require broader geographic sharing of donated livers, resulting in saving the lives of approximately 100 patients per year, while also putting in place initiatives which, hopefully, will increase organ donation significantly.

Second, we committed to attempt to provide you with information relating to donation rates for livers at organ procurement organizations which are not associated with a liver transplant program compared to those that have such programs. In checking with CONSAD Research Corporation, we determined that UNOS has failed to make such data available either to the public or to CONSAD despite repeated requests. There is some UNOS data available which describes the composite procurement rates for organ procurement organizations for all organs (including both solid organs and tissue, bone etc.). That data indicates a very significant variation between OPO's but without data about procurement rates for specific organs, which UNOS refuses to make public, any more detailed analysis of the factors that relate to the differences is impossible.

Third, in response to Mr. Reed's question about the comparison of life expectancies between a Status 1 patient who receives a transplant and a Status 3 patient, we discussed both life expectancy and survival rates. Because a Status 3 patient is not nearly as sick as a Status 1 patient at the time of transplant, a Status 3 patient has a predictably higher survival rate (80.9% 1 year graft survival rate) than a Status 1 patient (60.1% 1 year graft survival). However, it is important to note that after one year the proportion of patients alive remains essentially the same for all statuses. For example, approximately 5% of liver transplant patients who have survived one year have died by the second year regardless of status; an additional 2%-3% have died, again regardless of status, after surviving 2 years but before the third year, and so on. The survival rates for all liver transplant patients, even those within seven days of death at the time they receive a transplant, are quite good, especially when you consider that transplantation is a life saving operation. As we mentioned in the meeting, if the goal were to transplant those patients with the best chance of survival, the medical priorities

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established by the transplant community would be completely reversed, and those patients least in need of a transplant would receive the first priority. The goal of liver transplantation, however, is to save the lives of those patients who have no other alternative. Thus, the medical priority of transplanting the sickest patients first is appropriate.

And finally, allow me to draw your attention to the attached Code of Medical Ethics, published by the American Medical Association, Council on Ethical and Judicial Affairs, 1996-1997 Edition, Section 2.16(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." (Emphasis added). With a cold ischemic time of from 12-18 hours for donated livers, there is literally no part of the United States from/to which a donated liver cannot be transported for transplantation. The current UNOS system of organ allocation, which traps livers in 70 small geographic areas, is, at the very least, ethically questionable and, quite simply, bad public policy.

Again, we thank you very much for your questions, comments, and observations during our meeting and for your attention to this very important issue. As Mr. Fiske said in the meeting, and as other patient advocates have said in other forums, UNOS and the transplant centers who are its members, are fully capable of being involved in this discussion and looking out for their own self-interests. Someone else must protect the interests of the patients in making sure that the system is fair. That "someone" is the Department and this Administration.

If there is other information or data which we can provide to you, please do not hesitate to contact me.

Sincerely,



—David M. Matter

DMM:tn

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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-

2.15:

2.165

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*Original
of James Lee*

Douglas W. Hanto, M.D., Ph.D.
Associate Professor of Surgery

December 2, 1996

The Honorable Donna Shalala
Secretary of Health and Human Services
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Room 615F
Washington D.C. 02201

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.

cc: Philip R. Lee, M.D.
Judith Braslow
Walter Graham
James Burdick, M.D.

M. Michael I. Abecassis, M.D.
Northwestern Memorial Hospital
Children's Memorial Hospital

Marwan S. Aboutjoud, M.D.
Henry Ford Hospital

Mark B. Adams, M.D.
Froedtert Memorial Lutheran Hospital
Children's Hospital of Wisconsin

Prabhakar Baliga, M.D.
Medical University of South Carolina

Frederick Bentley, M.D.
University of Louisville
Kosair Children's Hospital

J. Philip Boudreaux, M.D.
LSU Medical Center, New Orleans
Children's Hospital
Mercy Baptist Hospital

John J. Brems, M.D.
Green Hospital of Scripps Clinic

J. Steve Bynon, Jr., M.D.
University of Alabama Hospital

Pierre-Alain Clavien, M.D.
Duke University Medical Center

A. Benedict Cosimi, M.D.
Massachusetts General Hospital

Stephen P. Dunn, M.D.
St. Christopher's Hospital for Children

Bijan Eghtesad, M.D.
Un. of New Mexico Health Sciences Center

Jeffrey H. Fair, M.D.
University of North Carolina at Chapel Hill

Ronald M. Ferguson M.D., PH.D.
The Ohio State University Hospital
Children's Hospital

Ronald S. Filo, M.D.
Indiana University School of Medicine

Robert Fisher, M.D., FACS
Medical College of Virginia

Jameson Forster, M.D.
University of Kansas Medical Center

Osama Gaber, M.D.
Santiago Vera, M.D.
William F. Bowld Hospital
Le Bonheur Children's Medical Center

Robert Gordon, M.D.
Emory University Hospital

Glenn A. Halff, M.D.
Medical Center Hospital

Douglas W. Hanto, M.D., Ph.D.
University of Cincinnati Medical Center

Daniel H. Hayes, M.D.
Carolinas Medical Center

Richard Howard, M.D.
Shands Hospital at the University of Florida

Todd K. Howard, M.D.
Barnes Hospital
Jewish Hospital
St. Louis Children's Hospital

Roger L. Jenkins, M.D.
New England Deaconess Hospital

Munci Kalayoglu, M.D.
University of Wisconsin Hospital & Clinics

Igal Kam, M.D.
University of Colorado Hospital

Frederick M. Karrer, M.D.
The Children's Hospital of Denver

Eliezer Katz, M.D.
Oklahoma Transplantation Institute

Andrew S. Klein, M.D.
Johns Hopkins Hospital

Baburao Koneru, M.D.
University of New Jersey Medical School

Ruud A.F. Krom, M.D., Ph.D.
Rochester Methodist Hospital

Mark I. Lorber, M.D.
Yale-New Haven Hospital

Cosme Manzarbeitia, M.D.
Albert Einstein Medical Center

Maureen Martin, M.D.
University of Iowa Hospitals & Clinics &

John McDonald, M.D.
LSU University Medical Center, Shreveport

William D. Payne, M.D.
University of Minnesota

James D. Perkins, M.D.
University of Washington Medical Center and
Children's Hospital and Medical Center

C. Wright Pinson, M.D.
Vanderbilt University Medical Center

Raymond Pollak, M.D.
University of Illinois Hospital

Timothy L. Pruett, M.D.
University of Virginia Health Sciences Center

Hector Ramos, M.D.
Tampa General Hospital

John M. Rabkin, M.D.
Oregon Health Sciences University

Dinesh Ranjan, M.D.
University of Kentucky Medical Center

Frederick Ryckman, M.D.
Children's Hospital Medical Center

Dale A. Rouch, M.D.
Methodist Hospital of Indiana

James A. Schulak, M.D.
University Hospitals of Cleveland

Timothy R. Shaver, M.D.
Fairfax Hospital

Harvey Solomon, M.D.
St. Louis University Medical Center
Cardinal Glennon Children's Hospital

John B. Sorensen, M.D.
LDS Hospital
Primary Children's Medical Center

Howard Takiff, M.D.
Alton Ochsner Medical Foundation, New
Orleans

Lewis W. Teperman, M.D.
New York University Medical Center

J. Richard Thistlethwaite, Jr., M.D., Ph.D.
University of Chicago Medical Center

Hillel Tobias, M.D.
New York University Medical Center

Jeremiah G. Turcotte, M.D.
University of Michigan Hospitals

David Vogt, M.D.
The Cleveland Clinic Foundation

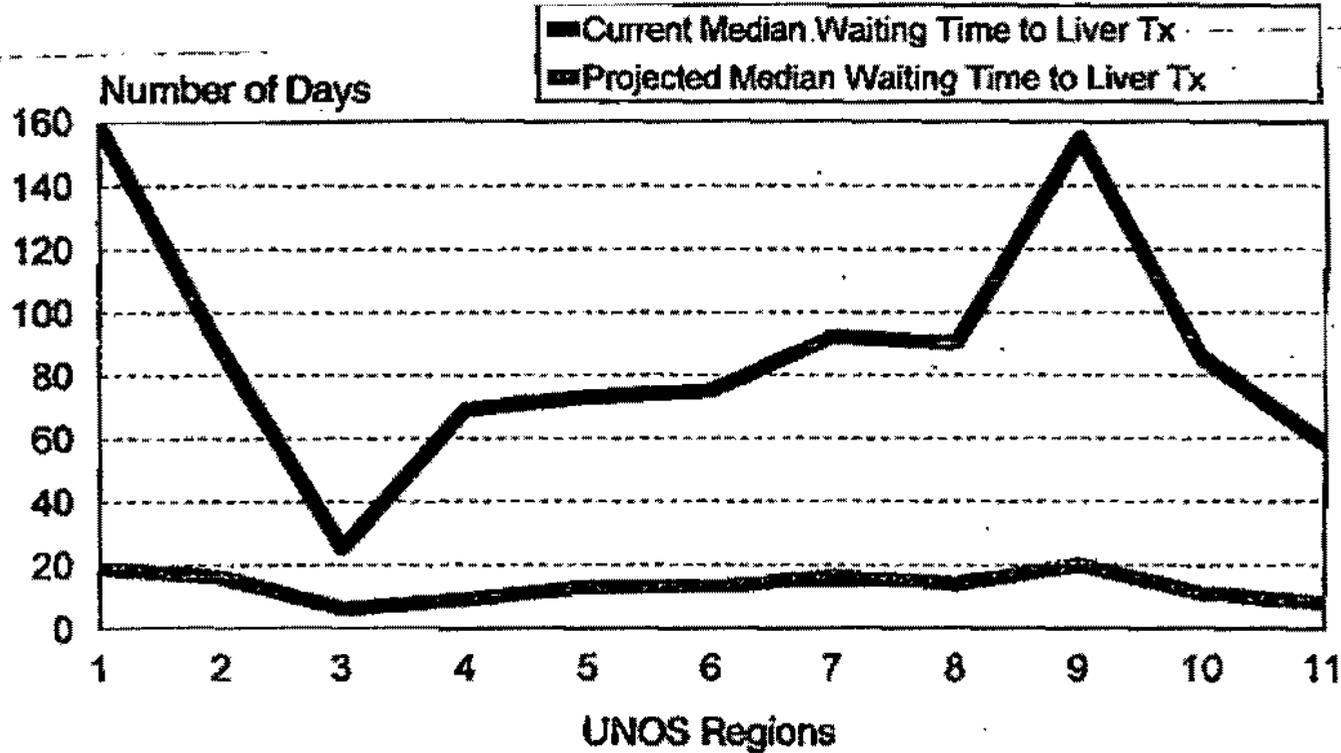
James W. Williams, M.D.
Rush-Presbyterian - St. Luke's Medical
Center

Linda Wong, M.D.
St. Francis Medical Center

R. Patrick Wood, M.D., FACS
UT-Houston Medical School, Hermann
St. Luke's Hospital
Texas Children's Hospital

Nasih Zuhdi, M.D.
Oklahoma Transplantation Institute

Regional Waiting Time Comparison

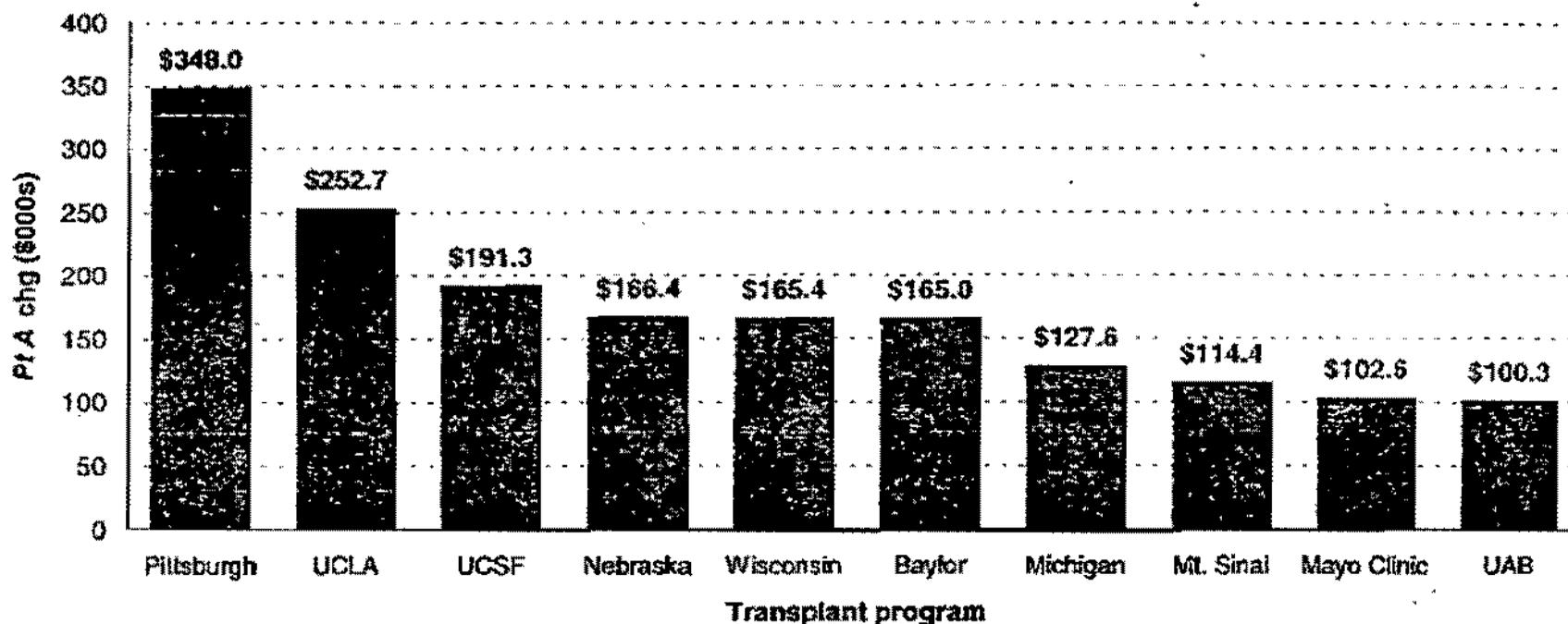


1992-94 Actual results vs. UNOS projections based on liver recovery rates at all OPOs being equal to the top OPO. Recovery rate for 1995: 30 donors per million and 80% liver recovery.



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

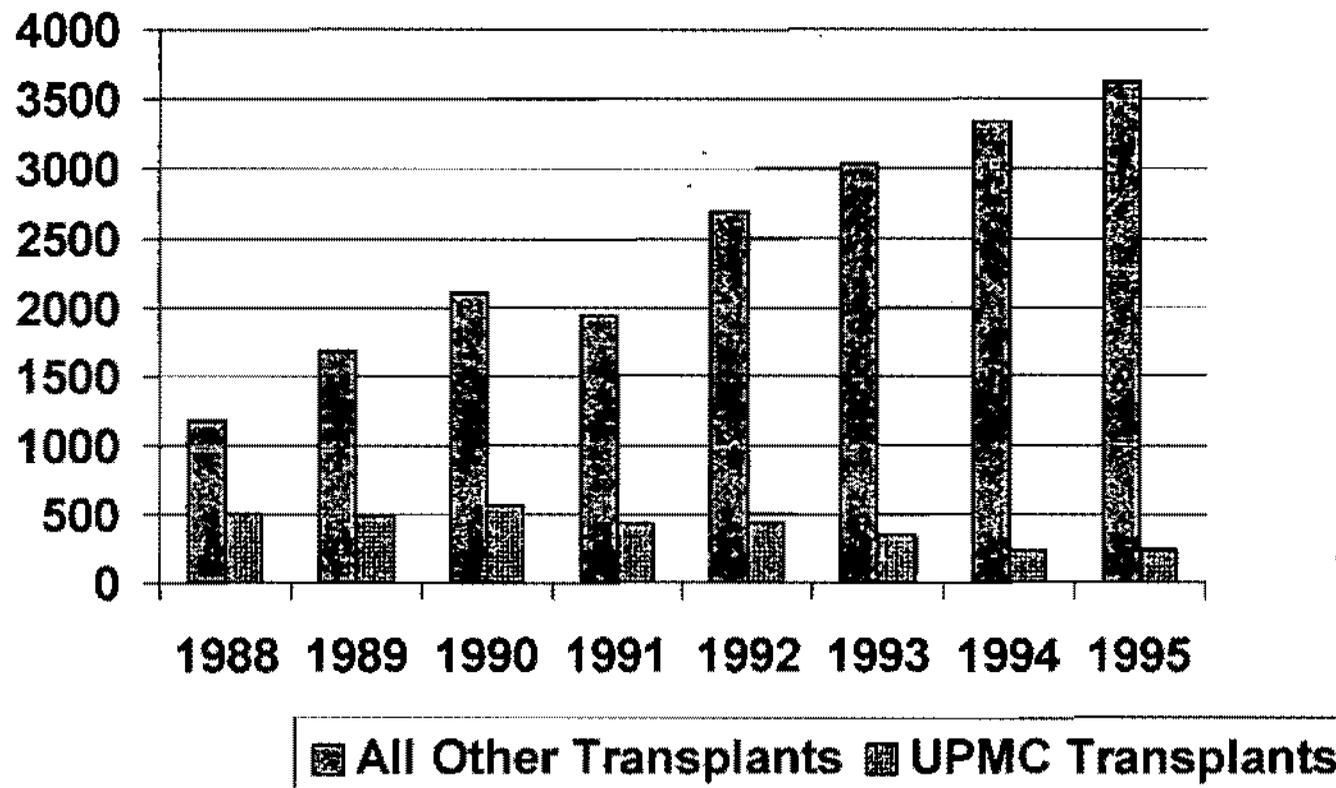
Liver Transplantation at Major Programs in United States



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



Liver Transplants Performed 1988-1995



CM -
Ask EK if it's appropriate
for us to have such a mtg.
If so, I'm happy to do it.
BR

March 25, 1997

MEMORANDUM TO BRUCE REED
CHRIS JENNINGS
FROM: BRUCE R. LINDSEY *BR*
SUBJECT: LIVER ALLOCATION POLICY

Boruce
As long as comat's
office has approved -
which comat's
office clearly has -
It's
OK.
EJ

As you may know, David Matter has written the President on several occasions about UNOS liver allocation policy. His first letter (copy attached) was the impetus for Secretary Shalala's decision to hold hearings on the liver allocation procedures. In response to his most recent letter (copy also attached), President Clinton has asked "What is right on the merits? Should we give to Chris Jennings to review?"

It is my understanding that in December 1996, Carol Rasco and Chris met with Watson Bell, his wife Jean Ann, and Walter Graham to discuss UNOS' position. David Matter would like to meet with the two of you to make the case for a wider geographic sharing proposal. Besides the two of you, the persons attending the meeting would include:

- David Matter
- John Tisdale
- Liz Dunst
- Nancy Granese, and
- Charles Fiske

Time is of the essence because H.H.S. is currently reviewing this matter. Are the two of you available next week? If so, when. Jennifer Dudley will follow up.

Thanks.

CM -
Ok, let's do it.
BR

Withdrawal/Redaction Marker

Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. note	Phil Caplan to POTUS re: Liver Transplant Issue (1 page)	2/12/97	P5

**This marker identifies the original location of the withdrawn item listed above.
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COLLECTION:

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Bruce Reed (Subject File)
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FOLDER TITLE:

Health Care-Organ Transplants [1]

rs83

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

- P1 National Security Classified Information [(a)(1) of the PRA]
- P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
- P3 Release would violate a Federal statute [(a)(3) of the PRA]
- P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
- P5 Release would disclose confidential advise between the President and his advisors, or between such advisors [(a)(5) of the PRA]
- P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.

PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).

RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

- b(1) National security classified information [(b)(1) of the FOIA]
- b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
- b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
- b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
- b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
- b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
- b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
- b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

Acc'd 2-10-97
10:00am

David M. Matter
501 UNDERCLIFF ROAD • PITTSBURGH, PENNSYLVANIA 15221

THE PRESIDENT
2-10-97

February 7, 1997

**Via Facsimile: 202.456.6703
and Federal Express**

President William J. Clinton
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

Dear Mr. President:

I'm terribly sorry to add to your unbelievably crowded agenda, but we're at a critical point in the liver transplantation debate within HHS and I'm afraid if we don't act now we may forever lose the opportunity.

As you know, my letter to you on this subject last fall eventually led to three days of public hearings conducted by HHS in December. Donna Shalala promised in her response to me on your behalf to determine on the basis of the public hearings which liver allocation policies promised the best results for the patients of America and to embody that decision in a final rule for submission to OMB.

Simply stated, my fear is that because there are many more small transplant centers than large and each of them has lobbied their Congressmen and Senators in opposition to a policy change and even to HHS's intervention, the Department is beginning to get "cold feet."

After having studied this issue in great detail over the past year, there is absolutely no doubt in my mind that the position of the University of Pittsburgh Medical Center (and several other large transplant hospitals) is the correct one. Allocating livers to the sickest patients first on the widest geographic basis possible is what our national policy should be with respect to the allocation and distribution of human livers.

President William J. Clinton

February 7, 1997

Page 2

The private contractor, the United Network on Organ Sharing (UNOS), hired by HHS to operate the organ procurement and transplantation network, is by any other name a trade association controlled by small transplant centers (one center, one vote) operating largely on the basis of self-interest. If they were steel producers or communications executives sitting around the table carving-up the market, the federal government would intervene in a heartbeat. Because they are "medical professionals" HHS seems reluctant to intervene. But if it doesn't no one will, and patients will continue to suffer the consequences.

The facts, as I see them, are pretty clear. HHS has in the past essentially relinquished its oversight and regulatory responsibility with respect to organ procurement, allocation and transplantation to an industry trade group incapable of making a decision without an inherent conflict of interest. UNOS has established liver allocation rules that literally trap organs within artificial geographic boundaries, which has had two profound effects: 1) patients with liver disease who are not hospitalized and are in relatively better health often receive livers in one region when just an hour away by plane a patient lies dying in intensive care; and 2) the number of liver transplant programs has nearly doubled to 119 today, i.e. new programs can start because they know they will have a reliable and predictable supply of organs. It doesn't matter how proficient they are at transplantation or whether having such a large number of centers is an efficient and effective way to deliver health care.

Each of these centers, no matter how few transplants they do or how awful their success rates may be, have the same voice and vote in UNOS as does a major, highly proficient center that does 100 or more transplants a year. Decisions are made by majority vote, so the system will never be changed by a trade association the majority of whose memberships may be disadvantaged by a change. Meanwhile, 50-100 people die unnecessarily each year from liver disease; 2,000 patient life years are lost; and, horrifically unequal waiting times for transplant will continue.

I have enclosed copies of the five part series on organ transplantation published earlier this week in the Cleveland Plain Dealer. They are extraordinarily well-researched and a very important

President William J. Clinton

February 7, 1997

Page 3

contribution to the national debate. After reading them, I believe, any fair-minded person would conclude that the system is broken, UNOS does not represent the interests of patients very well, and the federal government has not properly performed its regulatory and oversight role. Although the articles are quite lengthy, I've included them in their entirety and have highlighted several relevant paragraphs in each for easy reference (the first such notation appears on page 11).

I don't want in any way to abuse our friendship over a substantive policy issue, but I feel so strongly about this that I just had to bring it to your attention again with a personal letter. Initially I was dragged into this debate quite reluctantly, but as time has gone on I have come to realize that it may be the most important thing I've done in my life. I'm sorry for the length of this letter and for imposing on you again, but I don't know where else to turn.

Regards,

A handwritten signature consisting of a large, stylized capital letter 'D' with a small vertical stroke inside it, followed by the lowercase letters 'dwl' in a cursive script.

Waiting for the right person to die

One heart patient's
Cleveland Clinic
drama

First of five articles

By TED WENDLING,
JOAN MAZZOLINI
and DAVE DAVIS

PLAIN DEALER REPORTERS

For 99 days, Linda Robinson had been waiting for someone to die.

On the night of Aug. 26, as Linda went about the monotony of tidying up her room on the ninth floor of the Cleveland Clinic and preparing for bed, a representative of LifeBanc was phoning Teresa Duke, the Clinic's thoracic organ coordinator. A 44-year-old woman in Columbus had died of a stroke and her family had agreed to donate her organs.

In an act of pure altruism by grieving strangers, a heart, matching Linda's in blood type and size, was being offered to the Clinic for transplantation. The heart was the first match the Clinic had been offered for Linda since her hospitalization May 20.

Although Linda's wait had been shorter than many Clinic heart transplant patients', the uncertainty had become nerve-wracking.

Just three days earlier, doctors had to shock her heart to stabilize her erratic heartbeat. The jolt left scars on her chest and back. It also left an indelible psychological scar, driving home the realization that, after two open-heart surgeries, her 37-year-old heart was not going to last much longer.

She urgently needed a transplant. And although she was not in the habit of wishing ill on others, that meant someone had to die. Soon.

Blind trust

Thirty years after South African surgeon Christiaan Barnard prolonged the life of a 55-year-old man for 18 days by performing the first heart transplant, the American public is as ambivalent as ever about the social, moral and psychological implications of transplanting the living organs of one person into another.

While the wizardry of modern medicine allows doctors to seemingly confer immortality on those whose vital organs have begun to fail, many people — often because of the distrust, ignorance or sheer grief of their survivors — continue to take those organs to their graves.

But while donations have remained relatively stagnant, the number of hospitals performing transplants has more than doubled since 1988. Because transplants have become so commonplace, the number of people who have died waiting for organs has doubled, too.

Hospitals, striving to remain competitive, raise their profiles in their communities and claim a piece of the multibillion-dollar transplant market, have spent millions of dollars to start transplant programs.

SEE LINDA/12-A

2

LINDA FROM I-A

Eight years ago, 118 hospitals were doing heart transplants. Today, there are 166. For liver transplantation, the number of programs has grown from 70 in 1988 to 118 today.

Likewise, the number of people waiting for an organ transplant has tripled, topping 50,000 last month.

Like Linda, most of those patients know virtually nothing about the hospitals, surgeons and national organ-allocation system charged with saving their lives, relying simply on blind trust.

"It's amazing to me," said Judith B. Braslow, director of the U.S. Department of Health and Human Services' Division of Organ Transplantation. "You hear people say, 'I heard he was a big doctor.' What's a 'big doctor?' It doesn't mean anything, but the average person doesn't want to know much.

"The average patient wants to go, get their transplant, get better and get off the list. They have one goal."

That's certainly true of Linda. When she entered the Clinic, she didn't know how many heart transplants the Clinic had done, what its survival rate was or how its waiting time compared to other transplant centers.

She also knew nothing about a troubling issue that centers don't discuss with patients: The number of hearts turned down, for medical or nonmedical reasons, that were later transplanted into patients at other centers.

"I just know it's something I've got to do to get out of here," Linda said. "I just want to make sure it's a good match."

Luckily for Linda, her insurance company, Travelers, has a contract with the Clinic's heart transplant program as one of its "centers of excellence." The Clinic has one of the top cardiac programs in the country, and its doctors performed 66 heart transplants in 1995, more than all but three other centers. The national average was 14.

Compared to the other programs, the Clinic also has a better one-year survival rate (89 percent vs. 82 percent), and a reasonable median waiting time (149 days); and turns down almost no organs for nonmedical reasons.

It's time

It was 1:20 a.m. on Aug. 27 when a nurse flipped the light switch in Linda's room, rousing her from a deep sleep. A Clinic heart procurement team would be flying to Columbus to take a look at the 44-year-old stroke victim's heart, which had been matched for Linda through the United Network for Organ Sharing. UNOS, an organ databank in Richmond, Va., has the federal contract to distribute organs nationwide.

"I can't believe it! I'm not ready!" Linda stammered as she tried to remember the phone numbers of the people she had promised to call. "I'm so scared. I can't believe it."

There was, of course, her husband, George, who was back in Tyrone, the small central Pennsylvania town in which she had grown up.

Also her mom, Rita Miller, who was staying at the Ronald McDonald House on Euclid Ave.

"George, it's time," Linda said, her voice quivering.

"Are you sure?" he answered, shaking himself awake. He began to cry.

"Please drive careful," Linda said. "I love you. I'll see you when I wake up."

George, 36, a self-avowed "old hillbilly," used to be a long-distance trucker. He quit after Linda was hospitalized, taking a local construction job so that he wouldn't be on the road if something happened.

Being a trucker, George had spent plenty of nights driving in the fast lane. But even making good time, the trip to Cleveland would be 4½ hours. He couldn't be expected to arrive before 6:30 a.m.

In Rita's room, the beeper the Clinic had given her finally went off. By the time a Clinic police officer delivered her to the hospital, she was frantic.

"I know we were waiting all

this time, but I'm so scared," she said. "I'm just hoping this heart likes her as much as she likes it."

Even though the hour was late, the ninth floor was abuzz with activity as the nursing staff prepared to move Linda to the cardiac intensive-care unit on the fifth floor.

"I'm hoping it all goes well because she's really a special person," said nurse Jennifer Ulman. "I don't know how I would tolerate being here day after day. She deserves to have a life. She's young."

Marion Grimaldi, another nurse, was beaming.

"For me, it's a really exciting time when somebody gets a heart," she said. "It's like you feel like they're going to have a baby or something. The hair goes up on my arms."

As Linda was being wheeled down the hall, her mind was racing. One foreboding thought lingered: What if this turns out to be a dry run?

A dry run is the ordeal of getting prepped for surgery, only to find out that the organ is unsuitable for transplant. Roughly one-fifth of the trips Clinic heart procurement teams make to inspect donor hearts turn out to be dry runs — the judgment call being made that, upon close inspection, the organ is too marginal to accept.

That's what had happened to Linda's friend, Nancy Vigneau. On Aug. 15, as Nancy, 46, was being prepped for a heart transplant, the Clinic's procurement team leader called from Columbus to inform Nancy's surgeon that the donor heart was damaged.

The psychological effect on Nancy had been devastating. Four days later, the Brooklyn woman suffered a heart attack. She subsequently underwent open-heart surgery in which she received a HeartMate, a mechanical device that temporarily aids the weakened heart in the absence of a donor.

"I wish she'd have got her heart, God love her," Linda said. "I just hope that doesn't happen to me."

The death watch

While the ICU nurses and an anesthesiologist prepped Linda, Rita sat alone in the waiting room, clutching a box of Kleenex.

The clock read 3:10 a.m. A "Taxi" rerun played on the overhead TV set as Rita dabbed at her eyes.

Watching her daughter struggle to live for so many years had taken its toll on Rita. Linda, the eldest of Rita's five children, had been stricken with undiagnosed rheumatic fever as a child and underwent open-heart surgery to replace a valve in 1972, when she was just 13. She subsequently suffered a stroke.

She recovered, but when she had another stroke in 1983, followed again by open-heart surgery and replacement of the same valve, it became apparent to Rita that if Linda was going to outlive her, she would need a new heart.

Linda has viral cardiomyopathy, an enlarging of the heart. It is the most common diagnosis among heart transplant patients, afflicting a little more than half of those who receive transplants.

Worrying about Linda had been enough of a burden, but Rita, who is 55 years old and divorced, also had her own health problems, having recently been diagnosed with cancer of the breast and lymph nodes. That required her to drive the 250 miles back to Altoona, Pa., for her chemotherapy treatments, after which she would return to Cleveland to be by Linda's side.

"This time, I really felt bad," she said of her latest chemo session. "I had to lie down when I got here. Two nurses up there [on Linda's floor] got me a bed."

Since Linda's hospitalization, Rita has been haunted by helicopters, wondering every time she hears the distinctive whap whap whap of the Metro Life-Flight chopper whether it carries "Linda's heart."

For some who wait, the death watch becomes a topic of gallows humor, said Teresa Duke, the Clinic's thoracic organ coordinator. A few patients cope with their fear and guilt, she said, by "joking around about sitting at their windows with binoculars, looking for motorcyclists" to crash.

The call

At 5:03 a.m., the phone rang in the ICU. Dr. James McCarthy, the surgeon who had flown to Columbus for the procurement, had bad news. The stroke victim's heart was no good.

In an instant, all the hope, ex-

citement and expectancy of a night of magic were replaced by a sorrow so profound it seemed as though everyone in the room had died at once.

"You're kidding," Rita said as she began to sob. "Oh baby girl, baby girl..."

Linda, the color drained from her face, stared straight ahead. "I've had bad luck for so long, I don't need any more," she said.

As she tried to comfort her mother, Linda thought of George, racing down Interstate 80 in the early-morning darkness, worrying about whether he was going to be late.

"He drove so far for nothing," Linda said. "I don't look forward to telling him. He's going to be so upset."

Room with a view

From the ninth floor of the Clinic's "G" Tower, home to those awaiting heart transplants, patients can contemplate the treetops and rooftops of the city's East Side and watch the traffic on busy Euclid Ave.

The perspective can be frustrating, but for patients who are tethered to IVs and rolling heart monitors, it offers a reprieve from

television and the obsessive attention they must pay to their huge daily doses of medication.

But that's not true for Linda, who with help from her mom, transformed the spartan hospital room into a makeshift home. Hundreds of get-well cards, drawings and photographs warmed the walls of G90-26.

"I got that 3-D puzzle," Linda had said on Day 90, pointing to her Cinderella's castle puzzle, one of many she had finished. "I told myself when I finish that puzzle, that night I'll get my heart. Well, that's been finished for a week, and I still don't have my heart."

Improvements in transplantation — new medications and ventricular assist devices, which keep failing hearts beating — have increased the short-term survival rate. Considered little more than experiments 15 years ago, heart transplants are routine enough today that their average \$250,000 cost is covered by Medicare, Medicaid and private insurance.

But with donor organs being so scarce, the rapid medical advances have brought with them bigger waiting lists, longer waiting times and a greater chance of

dying while waiting for an organ.

Eight years ago, four people died every day waiting for an organ. By 1992, that number was seven. Today, it is above nine.

Currently, more than 3,700 people are waiting for a heart transplant. Only 2,361 received one in 1995, and 770 people died waiting.

I'm on my way

Aug. 30 was a sweltering day in Tyrone, and George Robinson couldn't move from the living room couch. He had been thinking about mowing the lawn, but he couldn't snap out of his depression. All he felt like doing was lying around.

Since Linda's hospitalization, her doctors had been forced to shock her heart seven times to keep it going. "The nurses down there said they had never brought somebody back to life that many times," she had told George matter-of-factly.

George was still confident that Linda was in good hands, but she had been waiting in the hospital for a new heart for more than three months now. What if she died waiting? He would be alone.

George and Linda didn't have

children. Linda had learned the hard way that she would never be a mother, having been told only after a miscarriage at age 21 that the blood-thinning medication she had taken made it impossible. George was getting another ice tea when the phone rang. It was

2:30 p.m.

"Honey, it's time," Linda said, trying to conceal her fear. "Now don't get too excited. Remember what happened last time. They've got another heart, but they have to check it out."

The clock was running. Four-

and-a-half hours stood between them, so George didn't waste words.

"I'm on my way," he said. "I love you."

First, George had to pick up Rita. To save time, he decided to take the route that went by Ty-

rone Area High School. But it was Friday, and the school was playing its arch-rival, Bellwood, in football. It was a big event in the small town, and hundreds of people already had clogged the streets by 3 p.m.

"I told her that when I got the call, I'd be there before they took her in," George said, recalling his late arrival the morning of Linda's dry run. "No matter what, I'd be there."

Code Blue

Farley Lee was filling out paperwork at the Clinic's ninth-floor nursing station when Linda's heart monitor sounded. Linda had been working on another jigsaw puzzle — the same one she had been noodling over for two weeks — when she learned that a heart had been offered for her. Initially, she had taken the news calmly, but within minutes her heart was racing out of control.

Lee reached the room first, finding Linda on the phone.

"I don't feel good," Linda said.

"Get back in bed," the nurse ordered.

Linda's normal heart rate was about 90 beats a minute, but as the Clinic staff rushed into her room, they could see it was at 120 and rising. They put her on oxygen, started an EKG and called a "Code Blue." It was 3:05 p.m.

The nurses knew Linda was in trouble. They also knew there

would be no transplant that night if they couldn't slow her heart-beat.

When Linda's heartbeat reached 150, the paddles were brought out to shock her.

"It's the same rhythm you did last week on us," said Dr. Matthew G. Deedy. "You feeling OK?"

"Yep," Linda said weakly, the oxygen mask muffling her voice.

Linda was anxious, but she also was alert and responsive. Deedy decided to give her heart time to slow itself, rather than shock her or administer drugs. Either one of those measures could jeopardize her chances of undergoing a transplant.

By 4 p.m., Linda's heart rate had dropped to 119. It was a go.

Point of no return

Shortly after 6:30 p.m., the organ procurement team boarded Life-Flight, bound for Youngstown. The team was led by McCarthy, the surgeon who had decided that the heart offered for Linda three days earlier was unacceptable.

In the ICU, doctors and nurses once again began inserting an IV tube into Linda's jugular vein. Linda was awake during the procedure.

"Ben, if the heart's no good, will they electric-shock me again?" she asked Ben Meola, one of her nurses. "I don't want to be shocked."

"They'll make that decision then," he answered gently. "Think positively."

Dr. Robert W. Stewart, head of the Clinic's heart transplant program and the doctor scheduled to perform Linda's surgery, came in to introduce himself and tell Linda a little bit about what to expect.

Transplants are exercises in medical precision — from the seemingly interminable poking and prodding patients endure to the almost military-style police escorts procurement team members receive until the moment they enter the surgery room.

5

"You try to coordinate everything else so that the minute they're walking in with the [new]-heart, we're taking the old one out so that there's an exchange at that time," Stewart said.

"The critical decision is really made by the person who goes to get the heart," he added. "I'm very fortunate to have highly experienced guys like Jim McCarthy. I have no idea how many transplant runs he's been on. He can spot a bad heart at 20 feet. He also knows a good heart. And he knows the heart that isn't perfect, but is going to be good enough for us."

Linda was beginning to get groggy from the medication. Her eyes were slits, but she could still talk.

"I hope they wake me tonight," she said, her voice barely audible through the oxygen mask. "I want to wake up later and have this whole thing be over."

Denise E. Brainard, a transplant nurse who follows patients after surgery, tried to comfort her.

"I talked to Dr. Stewart and he said it looks like a real good heart," the nurse said.

"I don't want a bad heart," Linda told Brainard.

"Oh, we won't give you a bad heart. That's why there are dry runs. When we give you a heart, it'll be a good one."

"They said that other one was from a 44-year-old woman," Linda added. "I don't want a heart from a 44-year-old woman."

6

After going through all this, I want a young heart. I don't want a 44-year-old heart."

"Well, even if we give you a 44-year-old heart, you can be sure that it will be a good one. You should have a good weekend. What a nice [Labor Day] holiday present."

It was shortly before 8 p.m. when the staff assembled in the ICU to take Linda to the operating room. As they were preparing to move her, George and Rita arrived at the fifth-floor waiting room.

"They're wheeling her to the elevator," a nurse told him. "You can catch her there."

The reunion was brief and frenzied.

This was it, George thought. These were the people who were going to perform a miracle by giving Linda a new heart.

His own heart was in his throat.

"I got to see her for two minutes," he said. "That's all I wanted — just to let her know that we were there, that we love her."

Night owls

The heady success the Clinic's heart transplant program has enjoyed since its inception in 1984 has conferred godlike status on its three surgeons — Stewart, Nicholas Smedira and Patrick M. McCarthy. But it is the tireless and nerve-jangling efforts of Katherine J. Hoercher, the cardiac transplant coordinator; Duke, the thoracic organ coordinator; and the Clinic's organ procurement teams that are perhaps even more impressive.

One of the grim realities of organ donation is that many organ donors die at night, often from homicides or traffic fatalities. That requires Duke, Hoercher and the procurement teams to be available around the clock.

As a result, they learn to take power naps, sometimes aboard Life-Flight.

"Transplants aren't really any fun because they're often in the middle of the night," said Hoercher. "But we're very aggressive. We take a lot of hearts that other programs turn down."

Stewart said the Clinic is acutely aware of the balance of risk factors.

"I will transplant a high-risk recipient," he said. "I will also use a donor that is borderline. But I won't use a borderline heart in a high-risk recipient. Risk is cumulative. And we can neutralize one risk factor by having everything else lined up very nicely."

Patients don't realize it, but even the nation's top transplant centers turn down more than 80 percent of the hearts they are offered, usually because the recipient is too ill or for any of more than a dozen other reasons involving the health and social history of the donor.

The determining factors in who gets transplanted are blood and tissue type, length of time on the waiting list, medical urgency and the distance the procurement team has to travel to obtain the organ.

Hoercher said the Clinic had traveled as far as northern Florida to pick up a heart. Because of the Clinic's willingness to accept hearts that other transplant centers turn down, 60 percent of its hearts come from outside the region.

The Clinic also transplants patients who are on its waiting list but are hospitalized out of state, bringing them in by helicopter for the surgery so that they can be near their families while they wait.

That wasn't possible for Linda, who had to quit her job at Josten's Yearbook Co. in State College, Pa., after she became too ill to work. So instead of being hospitalized in nearby Altoona, she spent her summer in Cleveland, staring out her hospital window and waiting for the death of a stranger.

The turning point

The temperature in the operating room was a cool 60 degrees when Stewart walked in wearing white pants and a white short-sleeved shirt. The call had arrived. The heart was good.
SEE HOSPITAL/14-A

HOSPITAL FROM 13-A

While teams of procurement specialists, who had arrived to claim other organs, hovered over the donor in Youngstown, the Clinic's surgical team readied an unconscious Linda for her five-hour surgery.

The heart is always the first organ to be procured, and doctors have a maximum of six hours after "cross-clamp" — the cutting off of the blood supply to the donor heart — to transplant the heart into the recipient.

By 10:22 p.m., it was clear that the procurement team was running later than expected. Linda's chest was open and Stewart was ready to remove her heart. She had been on the heart-lung bypass machine for 12 minutes.

"They didn't forget where we were, did they?" Stewart joked dryly.

Three minutes later, McCarthy and the procurement team swept into the room, carrying Linda's new heart in an Igloo Playmate cooler.

It took Stewart about three minutes to remove Linda's heart. Simultaneously, two nurses carefully removed the donor's heart — which was suspended in a saline solution — weighed it and prepared it for transplant.

Then the delicate work of stitching the new heart into Linda's chest began.

Stewart said little. Because the Clinic averages more than one heart transplant a week, team members have spent a lot of time working together.

The turning point in the surgery came when Stewart was ready to allow partial blood flow into Linda's new heart. It would either begin beating on its own or he would have to shock it back to life.

Or Linda would die.

The doctor removed the clamp. Immediately, the heart began beating, confirming Stewart's intuition: A perfect match.

"That restores my equilibrium," he said.

He asked a nurse to call George and Rita in the waiting room and tell them the surgery was going well. Rita began to cry. George, for the first time, saw an end to Linda's long ordeal.

"I can't help but think about where the heart came from, and why things have worked out this way," he said, his eyes focused on the floor. "I guess only one Man knows for sure. Still, I think about it, about the family on the other end of this."

Back to Tyrone

Nestled in the hollows of central Pennsylvania, hard by the Little Juniata River, Tyrone is a world away from Cleveland.

This mill town of 1,800 residents is where Linda grew up, and where her children would have grown up had her fortunes been different. Lacking though it may be of the amenities she and Rita had grown used to in Cleveland, Tyrone is where her family and her heart is.

For the most part, Linda has been doing well since her transplant. She is also relieved to hear that Nancy Vigneau, her friend at the Cleveland Clinic who was kept alive by the HeartMate, got "her" new heart a week before Thanksgiving, and that Nancy is recovering, too.

Because she has been so fixated on living, Linda has given little thought to what Renee Fox, a professor of sociology at the University of Pennsylvania, calls "the tyranny of the gift" — the inability of organ recipients to ever repay such an extraordinary act of giving. She was allowed only to send a brief thank-you card to the donor's family — who chose not to respond — and that was the end of it.

Like many transplant recipients, Linda expected her life to pretty much return to normal after she came home. It hasn't.

Every day, she checks her blood pressure, temperature and weight, walks 30 laps (five miles) around the interior of the high school and swallows 23 pills, ranging from anti-rejection drugs to Geritol. She returns to the Clinic every three weeks for a biopsy.

"My body's fighting my heart because it knows it's not part of my body; it's someone else's," she

said. "It was a good match. Best I've seen in some time."

Stewart said he was optimistic about Linda's long-term outlook. Her chance of surviving the first year, he said, was about 95 percent.

"The real question now is what's going to happen to the donor heart, specifically coronary artery disease," he said. "And there's about one chance in three that, five years from now, that will have caused her major problems, either death or re-transplantation."

While those odds may not sound great, most heart transplant patients will take them any day over the immediate alternative — death. Many heart recipients are now living more than 10 years. And the longest-living recipient, a 40-year-old patient transplanted at Stanford University in 1974, has logged more than 20 years.

"Every year, things get a little bit better," Stewart added. "So the outlook's not bad for Linda at all."

Linda's recovery was swift. On Sept. 7, eight days after her transplant, she left G90-26.

She tried not to cry, but even the heavens wept. The rain came in torrents as Linda, Rita and George loaded boxes into George's truck. Linda's nurses,

"Do you think they would get us in touch with them? If they had hard feelings, I wouldn't want to intrude on them," he said as his eyes welled with tears.

For a moment he could not speak.

"I'd like to let them know what we're like, to thank them very much for the second chance they gave my wife."

The Robinsons know only that Linda's new heart came from a 31-year-old woman who died from a gunshot wound. They now know that at least two other families benefited from the donor family's generosity, with the liver and kidneys also being procured for waiting patients.

Although organ recipients are given no other information about the donor, they are allowed to send a letter, usually relayed through the hospital or organ bank, to the donor's family. The family then chooses whether to respond.

Many don't, preferring their gift to remain a silent, selfless act.

'Bye bye, y'all'

At 1:04 a.m., the surgery ended. Stewart walked into the waiting room and extended his hand to George.

"It went very well," the doctor

many of whom made it part of their daily rituals to take their breaks in her room, gathered to say goodbye and wish her well.

"It was hard to leave those people," Rita said. "You get really close after being with them all that time."

"I didn't even see my cousins as much as I saw those people," Linda added. "I saw them every day."

And then she left, carrying the heart of a woman she had never known, along with the hopes and fears of a life she almost lost.

All that was left of her 110-day stay at the Clinic was the note she had scrawled on the message board in her room:

"Thanks for all the special care, EVERYONE. Bye bye, y'all."

said. "But I didn't think I would have to take all the medicine I take. I take a lot more medicine than I took before, and that burns me out a lot."

But in other ways Linda's life has returned to normal. Sweaters still needed to be cross-stitched for Christmas presents and the many chores associated with maintaining the Robinsons' small trailer home had to be done.

George hasn't been around to help much. After Linda came home, he took a job with a Conrail subcontractor, helping to clean up train-derailment sites. The money's good, Linda said — \$10 an hour — but it keeps George away from home a lot.

But there's a more important reason Linda has not had time to convalesce. It is now her turn to take care of Rita, who has been suffering terribly from her cancer.

Since completing her chemotherapy regimen, Rita has been receiving radiation therapy at Altoona Hospital. Every day, a hospital van makes its rounds through the hollows near Tyrone and its surrounding communities, picking up cancer patients and delivering them to the hospital's cancer center.

The patients with early ap-

pointments simply sit and wait until everyone is done. Then they are delivered back to their homes, where they wait until the van arrives again the next morning.

Linda vowed that her mom would not be on that van. So, every day, she drives Rita to the hospital, doing her cross-stitching in the lobby while Rita gets her radiation. Then they go bargain-hunting.

"She stayed with me the three months in Cleveland," said Linda. "I think I can get out and take her to the hospital."

These are precious months for Linda and Rita, filled with laughter and Rita's infectious optimism. For the first time in years, it appears that daughter will outlive mother — as every parent knows it should be.

And still, Linda isn't sure she would be willing to endure it all again.

"They say you might have to have another transplant within a certain time, but I don't know if I'd do it again," she said. "I say that now, but when it came down to dying at the hospital, I didn't want to."

"I guess I can say I wouldn't do it again, now that I'm doing so good."

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**FOR YOUR
INFORMATION**

**If you are facing
a transplant**

When deciding where to go for a transplant, patients should consider the annual number of transplants a center performs, its mortality rate and the surgeons' experience, medical experts say.

Centers that perform large numbers of transplants tend to have better survival rates and are less likely to turn away donated organs matched for patients on their waiting lists, according to Dr. Robert W. Stewart, head of the Cleveland Clinic's heart transplant program.

"Volume almost answers everything else," he said. "If you wanted to pick a transplant center just on the available information, pick the top 20 according to [volume] numbers, and then go down the top 20 and pick them according to survival rates."

Volume and mortality data for transplant centers are published by the United Network for Organ Sharing in its "1994 Report of Center Specific Graft and Patient Survival Rates." The full report costs \$115 and can be obtained by calling 1-800-243-6667.

UNOS also provides mortality rates on up to 10 centers free of charge to transplant candidates who send a written request to: UNOS communications, P.O. Box 13770, Richmond, Va., 23225.

Information about a surgeon's experience must be requested from the transplant center.

Additionally, "Transplant News," an industry newsletter, offers in-depth coverage on the latest issues of interest to patients and transplant professionals. You can subscribe by calling 1-800-689-4262.

And computer users with access to the World Wide Web will find useful transplant information on homepages published by UNOS:

<http://www.ew3.gtt.net/unos>
and the U.S. Department of Health and Human Services' Division of Organ Transplantation:

<http://www.hrsa/dhhs.gov/bhrd/dot/dotmain.htm>

A look at fragile lives and a medical bureaucracy

The major problem in transplantation, those involved say, is the national organ shortage. That's true. But many people do donate, bestowing parting gifts — what biomedical ethicist Thomas H. Murray calls "gifts of the body" — on strangers without expectation of compensation or even thanks.

These gifts give people such as 37-year-old Linda Robinson, whose story appears today, a second chance at life. They also advance the science of one of medicine's most astonishing frontiers.

But there is a dark side to transplantation: A Plain Dealer investigation found wide disparities across the nation in the time patients wait for organs; higher mortality rates, on average, at centers that perform limited numbers of transplants; and centers that frequently reject healthy organs for nonmedical reasons.

The more than 50,000 patients waiting for organs don't have access to that information. The government agency responsible for ensuring an equitable national transplant program, and the contractor that maintains the data, refuse to reveal it. They claim that transplant centers haven't reviewed it, and might be unwilling to provide information in the

future if it was disclosed.

The Plain Dealer's series, "Transplanting Life — The Triumphs, The Traps, The Tragedies," begins today and runs through Thursday. We expect it will stimulate debate about the nation's transplant system, which relies on the trust of seriously ill patients and the generosity of strangers whose families have a right to know how their loved ones' gifts of the body are being used.

Tomorrow: Some transplant centers turn down many donor organs for nonmedical reasons.

Tuesday: For almost a year, University of Kansas Medical Center officials misled patients awaiting heart transplants by failing to tell them that the program was dormant.

Wednesday: No issue strikes more at the heart of the dispute over equity in organ transplantation than the gross disparity in waiting times.

Thursday: On average, patients who receive organ transplants at low-volume centers are more likely to die within the first year than those who undergo transplants at high-volume centers. Also, a chart showing the mortality rates, volumes and median waiting times at U.S. transplant centers.



12.
SECOND ARTICLE

TRANSPLANTING LIFE

THE TRIUMPHS, THE TRAPS, THE TRAGEDIES



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Chester Szuber embraces his wife, Jeanne, during a news conference at William Beaumont Hospital in Royal Oak, Mich., in 1994 after undergoing a transplant in which he received the heart of his daughter, Patti Szuber, now 60, was the only one of the 24 patients on Beaumont's waiting list who received a heart transplant that year.

Hospitals reject healthy hearts

Waiting patients not told

Second of five articles

By DAVE DAVIS,
JOAN MAZZOLINI
and TED WENDLING
PLAIN DEALER REPORTERS

ROYAL OAK, Mich. — The sum of Patti Szuber's donated parts was two eyes, two kidneys, a liver, 30 bone and tissue samples, and one beating heart.

In a wrenching, bittersweet story of love and death, the heart of the 22-year-old nursing student went to her father, and it made Michigan's tree farmer, Chester Szuber, the most famous heart transplant recipient in America.

Patti Szuber's tragic death in a car accident in Tennessee in Au-

gust 1994 and the transplantation of her heart into the chest of her ailing 58-year-old father also thrust the suburban Detroit hospital at which the surgery was performed into the national spotlight.

Chester Szuber had been waiting four years for a transplant, and William Beaumont Hospital in Royal Oak was inundated with calls from reporters and TV producers who wanted to tell the family's heartbreaking story.

But what Beaumont officials never told Szuber or any of the other 23 patients on their waiting list in 1994 was that the national shortage of donor organs wasn't the only reason they had been waiting so long for new hearts.

That year, Beaumont staff turned down for nonmedical reasons 101 offers of hearts suitable for transplant. The reasons for the turn-downs, as reported to the United Network for Organ Sharing by the organ banks that offered the hearts to Beaumont, were either "surgeon unavailable/program too busy" or "inadvisable."

Another 76 heart offers were turned down by Beaumont administrators in 1994 for medical reasons. They accepted just one — Patti Szuber's.

Beaumont wasn't the only program that was turning down heart offers for nonmedical reasons that year. While transplant professionals were publicly lamenting the shortage of donor organs, 28 of the nation's 167 heart transplant centers refused for nonmedical reasons 20 percent or more of the total heart offers they received during the last seven months of 1994, according to UNOS records. About 97 percent of those hearts were later transplanted into patients at other hospitals, a UNOS official said.

"I'm surprised that the numbers are that high," said Thomas H. Murray, director of the Center of Biomedical Ethics at Case Western Reserve University and one of several ethicists and doctors who said they were unaware of the practice. "You'd like to know what the circumstances were ... but if they can't give



ASSOCIATED PRESS

Patti Szuber, 22, died Aug. 18, 1994, in a one-car accident in Great Smoky Mountains National Park in Tennessee.

"You can count me among those who were surprised to hear that it happens at all. I assumed it was extremely rare, and it ought to be extremely rare."

Transplant professionals say a hospital's rate of turning down organs for nonmedical reasons is just one factor that patients should consider when choosing a hospital. Other important factors are a hospital's mortality rate and the median length of time its patients must wait before being transplanted.

TRANSPLANTING LIFE

THE TRIUMPHS, THE TRAPS, THE TRAGEDIES

Yesterday: When Linda Robinson's 37-year-old heart began to fail, forcing her to take up residence on the ninth floor of the Cleveland Clinic last May, she faced the transplant paradox: For her to live, someone had to die. For Linda and her family, the wait for a new heart was a frightening reminder of the fragility of life and a close-up look at one of modern medicine's most astonishing frontiers.

Tomorrow: During an 11-month period in 1994 and 1995, the University of Kansas Medical Center placed on its heart transplant waiting list, or evaluated for placement, 38 patients without telling them that they had little chance of actually receiving a transplant because internal squabbles had shut the program down. As two state investigations later verified, patients were deceived and university officials failed to act.

Wednesday: If you need a new kidney, the median waiting time for a transplant ranges from less than two months at a hospital in Fort Worth, Texas, to 858 days at a medical center in Hershey, Pa. The median wait for a liver transplant is 18 days at a medical center in New Orleans but 648 days for the Boston hospitals that are served by the New England Organ Bank. In the continuing debate over equity in organ transplantation, no issue strikes more at the heart of the dispute than the gross disparity in waiting times.

Thursday: On average, patients who receive organ transplants at low-volume centers are more likely to die within the first year than those who undergo transplants at high-volume centers. Few patients are aware that they can significantly increase their chances of survival by going to a transplant center that does the risky surgery more frequently.

TURNDOWN FROM I-A

A center's high nonmedical turndown rate also doesn't necessarily translate into longer median waiting times for patients. In some cases, a high rate of turning down organs for nonmedical reasons simply reflects the size of a program and the resources the hospital has devoted to transplantation.

For example, of the 806 offers of hearts turned away for nonmedical reasons during the last seven months of 1994, many were refused by smaller programs, such as Beaumont's, which has just one transplant team. That means vacations, medical conferences and other cardiac surgeries that might call any member of the team away forced those centers to turn down hearts they otherwise might have accepted for waiting patients.

More recent turndown data could not be obtained because UNOS, the government contractor responsible for allocating donated organs, has refused to give 1995 and 1996 organ turndown figures for individual hospitals to the U.S. Department of Health and Human Services.

UNOS officials claim that transplant centers have not reviewed the figures and that the data may have been inaccurately or nonuniformly reported by the nation's 66 organ banks. They also fear that making the data public would discourage centers from voluntarily providing information, provoke lawsuits and change the way the data is reported in the future, rendering it scientifically useless.

Beaumont — which has done an average of just 2.6 heart transplants a year since its program opened in 1989 — had the third highest percentage of nonmedical turndowns in the country during



the last seven months of 1994. During that time, Beaumont turned down 52 offers of hearts for nonmedical reasons, an average of more than two per patient, UNOS records show.

In an interview in October, Beaumont administrators disputed the accuracy of the turndown figures. But last month, after referring the matter to the hospital's peer review committee, they confirmed that the figures were correct.

Hospital officials would not reveal the results of the committee's report, which was completed in December, but said they had addressed the problems and had not turned down any hearts in 1996 for nonmedical reasons.

"Nonmedical turndowns of hearts is something that we don't find acceptable around here, at least anymore," said hospital spokesman Mike Killian. "The issue is that it shouldn't have been done in the first place."

Beaumont administrators attributed part of the problem to the busy schedule of Dr. Jeffrey M.

TRANSPLANT FACTS

Estimated first-year charges per organ transplant, 1996

Heart	\$253,200
Liver	\$314,500
Kidney	\$116,100
Kidney/pancreas	\$141,300
Pancreas	\$125,800
Heart-lung	\$271,400
Lung	\$265,900

SOURCE: Millman & Robertson Inc., Brookfield, Wis., consulting actuaries

this issue, I say that UNOS ought to be publishing all of this," said Prottas, who teaches health politics at Brandeis University in Waltham, Mass. "It's really unfair. Everybody should know these sorts of things."

But they don't — particularly when organs are turned down for nonmedical reasons. Officials at Ohio State University Hospital, Vanderbilt University Medical Center and other transplant centers around the country all said they don't tell patients about non-medical turn-downs.

As a consequence, patients at Vanderbilt didn't know in 1994 that 41 percent of the heart offers were being turned down for non-medical reasons while the head of the Nashville, Tenn., hospital's heart transplant program, Bill Frist, was campaigning for the U.S. Senate.

Vanderbilt refused 93 offers of hearts in the last seven months of 1994, 46 of them for nonmedical reasons, according to UNOS data.

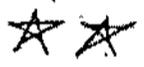
Frist, who was elected to the Senate that year, declined to comment for this story. Since becoming a senator, he has remained involved in transplant issues and, along with Ohio Sen. Michael DeWine, founded the Congressional Task Force on Organ and Tissue Donation.

It is unclear how many of the nonmedical turn-downs are attributable to Frist's absence, but hospital officials said that when he took a leave from Vanderbilt in late 1993, they were left short-staffed.

"When Frist left, it left two guys doing everything — all the adult heart surgery, all the adult thoracic surgery, and all the transplants," said Dr. Richard N. Pierson III, the current director of Vanderbilt's heart transplant program. "When I got here, I got that [turn-down] list from our cardiologist, who was unhappy that we had had to turn down organs because we didn't have enough people."

Pierson conceded that Vanderbilt turned down organs for non-medical reasons before he arrived in July 1994, but he disputed UNOS data stating that 39 of the 46 heart offers Vanderbilt turned down from July to the end of 1994 were because a surgeon was unavailable or the program was too busy. He said just one heart was turned down in 1994 because a surgeon was unavailable — in August of that year, while he was on vacation.

SEE ORGANS/7-A



Altshuler, the hospital's only heart transplant surgeon. Altshuler performs about 230 heart surgeries a year, or about four a week. When a heart is offered, he often must be available to remove as well as transplant it.

"The big problem in having one transplant surgeon is when I go on vacation ... what happens to the recipients?" Altshuler said. "We've made arrangements with other transplant programs now that if I'm gone for a week, we call them ... and they will cover for us."

Beaumont officials would not say whether any of the patients for whom hearts had been refused died without receiving a transplant. Because patient information is confidential, The Plain Dealer was unable to identify Beaumont patients or their survivors to interview for this story.

Patients not told

In a practice officials at Beaumont and some other hospitals said was universal, Beaumont did not tell any of the patients on its

waiting list about the nonmedical turn-downs. That deprived them of the choice of transferring to another heart transplant program.

Patients at Beaumont and elsewhere generally also aren't aware that transplant centers turn down most of the hearts they are offered for important medical reasons, such as the recipient was too ill or the donor's size or weight were incompatible with the recipient.

"There are always exceptions, but as a general practice, patients are not told about [organ] turn-downs," said Dr. Leslie Rocher, Beaumont's director of transplantation services. "It doesn't add to their well-being."

Some medical ethicists disagree. Jeffrey M. Prottas, a UNOS ethics committee member, even goes a step further — advocating that patients be given turn-down data when they are deciding where to have a transplant, rather than after they are already hospitalized.

"Whenever I have my say on



Transplant agency refuses to release information

ORGANS FROM 6-A

"Every program turns down organs," said Dr. John R. Wilson, director of Vanderbilt's heart failure program. "Whenever you have limited numbers of surgeons and you have patients on the waiting lists, you would not like to see any organ turned down. But that's just not a realistic expectation of any program. There is no program in this country that can guarantee that every organ that's acceptable is taken."

Aware of problems

Although heart transplant patients are not aware that many hospitals routinely turn down heart offers for nonmedical reasons, officials at UNOS and the Division of Organ Transplantation have known about the practice for almost two years.

In March 1995, prompted by questions about heart turndowns at the University of Kansas Medical Center, government officials asked UNOS to compile refusal data on each of the nation's 167 heart transplant programs.

The report, covering the last seven months of 1994, showed that the programs turned away for nonmedical reasons nearly 12 percent of all heart offers.

"Besides Kansas, there were a number of other heart transplant programs with high refusal rates," a Division of Organ Transplantation official wrote in an internal report. The report also said the turndown behavior at one hospital — Beaumont — appeared to fit the same "profile" as the University of Kansas.

The identification of that profile stemmed from a front-page story in the Kansas City Star in May 1995. The story reported that from April 1994 to March 1995, the center turned down all 50 hearts it was offered, most for nonmedical reasons.

Subsequent stories speculated that the turndowns may have contributed to the deaths of three patients, prompting an investigation by the state attorney general, numerous lawsuits and, ultimately, closure of the transplant program.

But information about Beaumont and the other hospitals with high heart-refusal rates was never made public, and federal regulators never pursued the matter, concluding that it was an unfortunate anomaly.

"There are about 850 transplant programs in the country and one, maybe two, have been brought to our attention as problems," said Judith B. Braslow, who heads HHS' Division of Or-

gan Transplantation. "We do 19,000 to 20,000 transplants a year. We're talking about very small numbers. That's not to say patients should have been treated this way."

But according to Braslow and her deputy, Remy Aronoff, no one, including anyone from UNOS, ever even questioned Beaumont or any of the other programs with high refusal rates.

One reason Beaumont wasn't scrutinized, according to Aronoff, was because the hospital's 1995 heart turndown figures improved over 1994. Beaumont's nonmedical turndown rate dropped from 50 percent in 1994 to 33 percent in 1995.

"That put them in a category with a lot of other programs, so we didn't pursue it further," Aronoff said.

Although previous contracts did not require UNOS to report potential problems to the government, a new contract UNOS and HHS signed Dec. 30 requires UNOS to monitor, investigate and report any incident "that jeopardizes the health of waiting list patients or transplant recipients."

Because few people are aware that hospitals turn down donor organs, few have been advocating that patients be told. The exceptions are the patients and families who waited in vain for hearts at the University of Kansas Medical Center.

"I absolutely believe that patients or their families have a right to know what's going on so they can discuss it and make better decisions," said Loetta DeWalt, whose husband died before he could receive a heart transplant at the medical center. "We were not told anything."

Teddy DeWalt, 60, a retired Kansas City firefighter, endured months of poking and prodding with the hope of getting a new heart. But in February 1994, while he was being evaluated for a transplant, his enlarged heart failed.

"He was told that it was time to go on life support," his wife recalled. "At the last minute, he

changed his mind, which was probably just as well since he would have been going to a place where they weren't even doing transplants.

"He died 10 minutes later."

Keeping secrets

With the exception of data involving Beaumont, UNOS officials have refused to release to the federal government or the public 1995 and 1996 figures showing how many hearts individual hospitals turned down for nonmedical reasons. They also have refused to release turndown data for other types of donor organs.

UNOS President Dr. James F. Burdick, a transplant surgeon at Johns Hopkins Hospital in Baltimore, said turndown figures were "not a very useful statistic" and should not be used to judge transplant center performance.

"If you want [to use the data] to say such-and-such center wasn't doing things right, I'm telling you, you're on thin ice there," Burdick said.

He added that giving patients information on organ refusals and median waiting times at transplant centers "don't help patients very much because, lo and behold, everybody's doing an excellent job."

"I think that in the big picture, the issue of releasing the data to patients is an idea that would be designed to fix something that isn't a big problem... If you're trying to talk about ways to help patients understand the national system, we've got many ways that we can help patients more than by giving them this data."

One way UNOS helps patients, Burdick and others say, is by publishing survival rates for all transplant centers in the United States. But that information is based on transplants performed five or more years ago. An updated survival report is due out this summer.

The limited data UNOS and the government have been willing to release shows that the problem of nonmedical turndowns of hearts has worsened since 1994.

On average, in the last seven months of 1994, centers refused for nonmedical reasons nearly 12 percent of all heart offers.

By the next year, that rate had increased to 25 percent. And in the first quarter of 1996, it had dipped slightly, but was still at 19 percent.

Not all transplant centers turn down large numbers of hearts for nonmedical reasons, however. Seventy-one hospitals managed to

TRANSPLANT FACTS

The length of time organs remain usable after procurement

Heart	4-6 hours
Lungs	4-6 hours
Pancreas	12-24 hours
Liver	16-32 hours
Kidney	48-72 hours

SOURCE: Center for Organ Recovery and Education

keep refusals for nonmedical reasons below 5 percent, according to the 1994 data. They included the Cleveland Clinic, where just 0.33 percent of the heart offers were refused for nonmedical reasons.

Dr. Robert W. Stewart, head of the Clinic's heart transplant program, attributed that number to the resources available at the Clinic, which performed 74 heart transplants in 1996, more than all but three other centers.

"We almost never would have to turn down a heart because we don't have the manpower," Stewart said. "You cannot, in a smaller institution, have the privilege of having three separate teams. If

you're just completing a transplant and they call you with another donor, you're probably not going to be able to use the people who are already doing that particular procedure. You're going to have to have an entirely new team standing in the wings."

Defining 'inactive'

Last summer, UNOS adopted a policy that calls for letters of inquiry to be sent to any program that turns down 10 consecutive organs. After some debate, it also decided that programs found to be "inactive" should inform their patients.

Left unaddressed were the issues of how long a center could go

without performing transplants before being considered inactive, and what to do about programs that weren't technically inactive but were turning down large numbers of organs and not telling their patients.

UNOS Executive Director Walter K. Graham would not say whether UNOS had sent letters of inquiry to any of its members.

Braslow, director of the Division of Organ Transplantation, supported the policy, but said she was not entirely satisfied.

"To me, it is unconscionable that a program should be inactive and the patients not be notified," she said. "There isn't one of us who would sit still for that if it were our spouse or our kid."



Contractor keeps government in dark on transplant data

By DAVE DAVIS
and TED WENDLING
PLAIN DEALER REPORTER

RICHMOND, Va. — For nearly two hours, Judith B. Braslow waited impatiently outside the closed meeting room as board members of the United Network for Organ Sharing met in executive session recently in Boston.

"I'm furious," she told anyone who would listen. "I can't believe they're doing this."

As director of the U.S. Department of Health and Human Services' Division of Organ Transplantation, Braslow heads an agency that regulates UNOS and supplied the nonprofit organization with about 18 percent of its \$13.1 million in revenue in 1995, according to UNOS' most recent income tax return.

In the curious world of transplantation, that hasn't given her the access she believes she is due.

"There's a lot of tension right now between the government and UNOS," Braslow said. "And that tension centers on where does our authority stop, and what do we have the right to get and what don't we have the right to get."

In recent months, the Richmond contractor has repeatedly told the government what it doesn't have the right to get: data on transplant centers' turndowns of organ offers, access to records and meetings of UNOS' Council on Organ Availability and, on occasion, even minutes of UNOS' public board and committee meetings.

Dr. James F. Burdick, a transplant surgeon and UNOS' president, acknowledged that tension exists between UNOS and Braslow's office. "I think there are people in the government who would like UNOS to be a lot less private," he said.

UNOS, which was formed in 1986 as part of a public/private partnership intended to manage the acquisition and distribution of the nation's scarce supply of donated organs, has made itself indispensable to the government. But after years of allowing UNOS



UNOS Executive Director Walter K. Graham: "I personally believe that the essence of democracy is self-regulation."



UNOS President Dr. James F. Burdick: "We've got many ways that we can help patients more than by giving them this data."

to operate a system in which compliance is voluntary and failing to enforce a key provision in one of its contracts with UNOS, Braslow's office increasingly finds itself helpless when UNOS says no.

Some people think the government has abdicated its responsibility.

"You can't delegate public policy to a private contractor," said Dr. John P. Roberts, a liver transplant surgeon at the University of California at San Francisco. "You can't have the people who are in control — essentially competitors — make policy."

UNOS Executive Director Walter K. Graham disagrees.

"I personally believe that the essence of democracy is self-regulation," he said. "That's what we do in this country . . . and that's what UNOS does, so I think it's a very good reflection of the whole principle of democracy in this country."

UNOS owes its clout to a pair of

three-year contracts it renewed last month for a total of \$6.07 million. Administered by HHS, one contract allows UNOS to operate the Organ Procurement and Transplantation Network, a 24-hour organ-placement system that matches donor organs with waiting patients. The other gives UNOS authority to run the Scientific Registry of Transplant Recipients, a database of medical information on people who receive transplants.

Those contracts have allowed UNOS to become the transplant community's most powerful player: a tax-exempt organization whose members include 281 hospital transplant programs, 55 laboratories, 66 organ banks and 29 medical/scientific organizations.

UNOS, which enjoys the overwhelming support of those involved in organ transplantation in the United States, is governed by a physician-dominated, 39-member board of directors that includes 11 members of the pub-





ASSOCIATED PRESS

Gwen Mayes, left, an employee in the federal Division of Organ Transplantation, talks to Judith B. Braslow, division director.

lic. Board members also include representatives from each of UNOS' 11 geographic regions.

Most decisions are reached by consensus through meetings of the 21 committees UNOS operates. Board members, who are not compensated but are reimbursed for expenses, also hire the executive staff, who run the day-to-day operations of the 164-employee organization.

Ninety percent of UNOS' budget comes from the two government contracts and the \$340-per-person computer registration fee that patients or their insurers pay to be placed on the national waiting list. The remaining 10 percent comes from member fees and other activities.

The national waiting list contains more than 50,000 registrations and receives about 7,000 new registrations a year.

Graham and other UNOS officials criticize the government for failing to pass regulations that would give UNOS legal authority to prohibit poor-performing transplant programs from receiving organs and take enforcement action against members who violate UNOS' guidelines.

But although Graham says the lack of regulations has left UNOS executives with "our hands tied behind our backs" because virtually all policies governing transplantation are voluntary, he, and other UNOS officials adamantly

opposed a recent move by HHS Secretary Donna Shalala to impose federal regulations on UNOS members.

Graham said UNOS was not objecting to government regulation per se, but said HHS' proposed rules "will basically do away with our standards ... so there is a huge philosophical difference."

While some HHS officials have become frustrated at their inability to force UNOS to provide data, some of those conflicts are due to the government's own inaction. A case in point is the OPTN contract, which, until it was rewritten last month, required UNOS "to establish an on-line data capability ... so that [HHS] shall have immediate access to OPTN data."

But government officials have never had that access. The reason? Braslow, citing a small staff and lack of technological expertise within her department, says she has never "exercised" that clause in the contract.

"It doesn't do me any good to have that on-line capability if I'm not going to use it," she said. "We can get whatever information we need. If I want to know how many people were transplanted in 1995 that have blue shirts, a mustache and a beard in the western half of this country, I can get that information [from UNOS], and I can probably get it within 24 hours."

Braslow made those comments last summer. Since then, UNOS

has repeatedly denied requests by her office for data listing the reasons transplant programs turn down organ offers. The Plain Dealer requested the information under the Freedom of Information Act for centers that transplant hearts, lungs, kidneys, pancreases and livers.

Last July, Braslow, Deputy Director Remy Aronoff and attorney David Benor agreed to request the data from UNOS and provide it to The Plain Dealer.

They backed down when UNOS objected to the newspaper's request. After the paper appealed the denial, Braslow made a written demand to UNOS for the data. On Jan. 15, Graham said no.

UNOS officials have repeatedly contended that the data are "misleading" and "meaningless" indicators of transplant centers' quality.

After several discussions with UNOS officials, however, Aronoff stated in different terms what he believed was UNOS' objection to release of the data.

"I had asked for the data you requested ... [but] they don't want to give us the data for the purpose that we're asking for it," Aronoff said. "They think if it's given out and publicized, it will jeopardize their ability to get that same data from their sources."

"Because it's potentially embarrassing?" Aronoff was asked. "Well, yeah, right."

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OFFERS OF HEARTS REFUSED FOR NONMEDICAL REASONS

Between June 1, 1994, and Dec. 31, 1994, the nation's transplant centers turned away about 83 percent of the offers of hearts matched to their patients. Nearly nine out of 10 times they did so based on a medical judgment, such as the recipient was too ill or the donor was the wrong size or weight. Most programs also refused heart offers for

nonmedical reasons - because the surgeon was unavailable, the hospital was too busy or for some other administrative reason. This chart includes only hospitals that received 12 or more heart offers during the last seven months of 1994, the latest period for which such information is available.

TOP 20

Hospital, City, State	Heart offers	Transplanted	Refused	Refused nonmedical	Percent refused nonmedical	Patients waiting
1 University of Kansas, Kansas City, KS	47	0	47	32	68.09	17
2 University of Maryland, Baltimore, MD	13	2	11	7	53.85	18
3 William Beaumont, Royal Oak, MI	106	1	105	52	49.06	23
4 Vanderbilt University, Nashville, TN	112	19	93	46	41.07	30
5 University, Lexington, KY	29	8	21	10	34.48	10
6 University of Iowa, Iowa City, IA	72	6	66	24	33.33	18
7 Henry Ford, Detroit, MI	37	10	27	12	32.43	17
8 Latter-Day Saints, Salt Lake City, UT	20	6	14	6	30	13
9 Methodist, Dallas, TX	18	2	16	5	27.78	6
10 University of Wisconsin, Madison, WI	59	32	27	16	27.12	39
11 St. Thomas, Nashville, TN	56	11	45	15	26.79	48
12 Johns Hopkins, Baltimore, MD	27	7	20	7	25.93	21
13 University of Alabama, Birmingham, AL	88	24	64	22	25	23
13 Hartford, Hartford, CT	20	7	13	5	25	19
13 University of Utah, Salt Lake City, UT	20	10	10	5	25	18
16 St. Francis, Tulsa, OK	25	9	16	8	24	20
17 Jackson Memorial, Miami, FL	71	9	62	17	23.94	13
18 Jewish, Louisville, KY	140	12	128	33	23.57	40
19 Newark Beth Israel, Newark, NJ	68	12	56	14	20.59	12
20 University, Denver, CO	35	17	18	7	20	13

BOTTOM 20

Hospital, City, State	Heart offers	Transplanted	Refused	Refused nonmedical	Percent refused nonmedical	Patients waiting
90 Sacred Heart, Spokane, WA	98	10	88	2	2.04	4
81 St. Joseph's, Atlanta, GA	58	9	49	1	1.72	35
82 Methodist, Indianapolis, IN	66	12	54	1	1.52	37
93 University of Virginia, Charlottesville, VA	73	20	53	1	1.37	34
94 Stanford University, Palo Alto, CA	435	22	413	3	0.69	33
95 Cleveland Clinic, Cleveland	303	36	267	1	0.33	42
96 Children's of Los Angeles, Los Angeles, CA	32	2	30	0	0	1
96 Loma Linda University, Loma Linda, CA	27	20	7	0	0	9
96 USC-University, Los Angeles, CA	18	3	15	0	0	10
96 Tampa General, Tampa, FL	47	12	35	0	0	14
96 Rush-Presbyterian-St. Luke's, Chicago, IL	24	14	10	0	0	18
96 New England, Boston, MA	15	3	12	0	0	14
96 Brigham & Women's, Boston, MA	45	14	31	0	0	14
96 Barnes, St. Louis, MO	32	14	18	0	0	46
96 Children's, St. Louis, MO	29	13	16	0	0	12
96 University of Mississippi, Jackson, MS	12	9	3	0	0	5
96 Medical College of Ohio, Toledo	25	3	22	0	0	18
96 Medical University, Charleston, SC	20	9	11	0	0	10
96 Methodist, Houston, TX	68	14	54	0	0	19
96 University, Seattle, WA	32	5	27	0	0	15

OTHERS IN OHIO

23 Children's, Cincinnati	17	2	15	3	17.65	1
75 Ohio State University, Columbus	127	8	119	5	3.94	31
85 University of Cincinnati, Cincinnati	81	18	63	2	2.47	17

Many donated organs are never transplanted

By TED WENDLING

STAFF WRITER

In phone conversations often held at night, organ bank donation specialists and hospital organ procurement coordinators carefully go over a standardized checklist.

Did the next-of-kin give written consent for donation? How did the donor die? Does the donor have a history of cigarette, alcohol or IV drug use? What medications were administered before the donor died?

Those and many other questions are asked of doctors, nurses and donors' families before an organ bank decides whether to offer an organ for transplantation. The information is then entered into the computer system of the United Network for Organ Sharing, which matches it against thousands of potential recipients on the national transplant waiting list. The matching process numerically ranks potential recipients based on their distance from the donor organ, the number of days they have waited, their medical status and other factors.

For a variety of reasons, many donated organs are never transplanted. For those that are, once the hospital verifies that a transplant was performed, the UNOS computer generates a form listing all potential recipients and sends it to the organ bank that procured the organ. The organ bank is required to show that the organ was offered to every patient ranked above the recipient, and to report the reason each hospital turned it down.

Collecting such data ensures that patients ranked higher on the waiting list were not skipped over because someone lower received unwarranted consideration.

Organs are rarely accepted on behalf of the first patient on the list. In 1995, for example, donor hearts were turned down by hospitals an average of six times before being transplanted. Three out of four times, they were turned down for medical reasons — ranging from issues related to the quality of the organ or the donor's social history to the recipient's immediate need for a multiple organ transplant.

The nation's 66 organ banks reported that another 3,448 heart offers — representing one-quarter of the 13,801 that were refused in 1995 — were turned down for nonmedical reasons, either because a surgeon was unavailable, the program was too busy or for other administrative reasons.

Some transplant physicians disagree with the way UNOS tallies turndown data. If, for instance, a hospital has three ranked patients on its waiting list that are matches for a heart and the hospital turns the heart down, UNOS counts it as three turndowns.

That's wrong, said Dr. Wayne E. Richenbacher, director of the heart transplant program at the University of Iowa Hospital.

"If you're offered a heart and turn it down, that's the end of it," he said. "That's one offer and one refusal."

Dean F. Kappel, president of Mid-America Transplant Services in St. Louis, said he would like to see medical and nonmedical turndown figures made public after being reviewed by the transplant centers. Kappel serves on the UNOS board of directors.

"I think it's really unacceptable if programs are consistently turning organs down," he said.

Hospital halts transplants, doesn't tell dying patients

Third of five articles

By TED WENDLING,
DAVE DAVIS
and JOAN MAZZOLINI
PLAIN DEALER REPORTERS

KANSAS CITY, Kan. — Two months after Adrienne Hart entered the hospital to be evaluated for a heart transplant, her mother leaned over her hospital bed and gave the 16-year-old honor student permission to die.

"I said, 'Honey, if you see a bright light and it feels good to you, you can go. I won't be mad at you,'" Janice Hart recalled. "She couldn't talk, but I knew what she was thinking: 'You mean I'm dying?'"

"I just couldn't come out and tell her that she was."

Hart's grief over Adrienne's Aug. 6, 1994, death didn't end with the funeral. A month later, her nephew, Raymond Price, 20, stricken by the same heart ailment that afflicted his cousin, was hospitalized for evaluation for a heart transplant in the same University of Kansas Medical Center intensive-care room in which Adrienne had died.

Told he had been added to the center's transplant waiting list, Raymond chose the option in November 1994 of waiting for a heart at home in King City, Mo., instead of the hospital, said his mother, Sherri Curtis. The following March, he was found dead on a waterbed in the home of a friend in nearby St. Joseph, Mo.

Hart and Curtis didn't know it, but the university's heart transplant program was dead, too. Even before Adrienne's death, it had fallen victim to an internal political struggle that saw program administrators turn down every one of the heart offers matched to patients on the center's waiting list, most of them for nonmedical reasons.

Officials at the two agencies that oversee the nation's transplant system insist that the University of Kansas Medical Center scandal was an isolated case. But their own records show that at the same time the Kansas story was unfolding in the local press, 27 other heart transplant programs around the country were turning down as many as one-fifth of their

heart offers for nonmedical reasons.

Until recently, none of that information was ever made public by the United Network for Organ Sharing or the U.S. Department of Health and Human Services, and neither agency made as much as a single phone call to the programs to inquire about the high nonmedical turnaround rates, officials at both agencies say. UNOS has been designated by HHS to manage organ transplantation.

In Kansas, as investigators would later conclude, patients were deceived, university officials failed to act and UNOS, lacking regulatory authority over its member institution, never notified state or federal authorities that there was a problem.

By the time Kansas' attorney general announced last August that the University of Kansas Medical Center and two foundations affiliated with the university had agreed to pay \$265,000 in restitution and penalties for "egregious behavior," Hart and Curtis had heard it all.

The sisters had heard the assurances of medical center personnel that Adrienne would be added to the waiting list as soon as her health stabilized. Curtis also remembered the contradictory statements of nurses, some of whom had falsely told her that Raymond had been added to the waiting list.

"I'm angry," said Curtis, who will use part of the settlement her lawyer recently negotiated to buy a tombstone for Raymond's grave. "I'm mad because if he had gone to St. Luke's [in Kansas City, Mo.], maybe he would have lived. To let our children die just because of a businesslike, money mentality — that's what gets to us."

Internal conflict

In investigations spurred by stories in the Kansas City Star, state authorities found that between Jan. 1, 1994, and March 31, 1995, the medical center placed on its waiting list, or evaluated for placement, 38 patients who had little chance of actually receiving a heart transplant. Thirteen of those patients have died.

SEE KANSAS/6-A

Patients, but no transplants

KANSAS FROM 1-A

Investigators found that problems at the medical center began in the spring of 1994, when several nurses, unhappy about a departmental merger, quit and others started refusing to work overtime. As a consequence, the two heart transplant surgeons, Drs. Jon F. Moran and Clay Beggerly, began to turn down heart offers for their patients, convinced that the number of remaining staff was inadequate and that they lacked proper training in post-operative care.

Although Moran detailed his concerns in memos he sent to his superiors, the staffing issue was never adequately addressed, and Moran continued to refuse hearts, the auditors said.

"As we talked with medical center officials throughout this audit... clearly, no one thought it was their responsibility to inform patients about the problems that continued to plague the program," a report by the Kansas Legislative Post Audit Committee said.

Investigators found that Dr. Steven B. Gollub, the medical center's director of cardiovascular medicine, deceived patients by leading them to believe the center was doing transplants and by falsely telling some patients that they were on the waiting list.

That's what happened to Cara Lee Gardner of Emporia, Kan., in July 1994. After three months of waiting, Gardner's husband, Bill, asked Gollub to refer his wife to another hospital. According to an affidavit Cara Lee Gardner provided to the attorney general's office, Gollub turned to the heart transplant coordinator and said, "Let's get her a heart real soon."

Gardner didn't know it then, but, according to a lawsuit she filed last July, her name wasn't even on the center's waiting list at the time Gollub is alleged to have made the comment. Although she was added the next month, the suit says, she later underwent triple-bypass surgery and was taken off the list.

Gollub and other university and medical center officials declined

to answer questions about the heart-transplant program, which has been closed.

"With the filing of litigation, we found ourselves in a delicate situation," university spokesman Randy Attwood said in a prepared statement. "Because of the legal element, we have declined further interviews."

Both Beggerly and Moran have left the University of Kansas. Beggerly declined to comment, but Moran, who filed a defamation lawsuit against the university and several of its officials last July, said he had been unfairly made a scapegoat.

"When I wanted to close the program at KU... I tried by every avenue my attorneys said was appropriate," he said. "I called UNOS. I went to the [medical center] chief of staff, I said, 'Please, let me close the program,' and I was refused permission to close the program."

"I could have resigned and I guess lots of ethicists would stand up and say... I was like the guard at Buchenwald. But I was trying to keep a program that had been very good either good or going, and there were other programs I was responsible for that were saving the lives of children in Kansas."

Did Budig know?

Problems at the medical center went far beyond Moran and Gollub. They extended to the office of former university Chancellor Gene A. Budig, whose name auditors placed at the top of a report listing 12 people "who were aware of problems in the heart transplant program but did nothing to address them."

Budig is now president of baseball's American League.

In an August 1995 interview with Kansas auditors, Budig said he was "not aware of any specific problems" with the heart transplant program and claimed he "wasn't aware that hearts were being turned down for other than medical reasons" until May 1995.

But state records show that between April and July 1994, Budig received four letters describing serious problems in the program.

The correspondence included a June 1994 letter from Moran's lawyer, who claimed that the medical center had "refused to confirm that its heart transplant program is on inactive status, thereby misleading the patients" and violating its agreement with UNOS.

Phyllis Merhige, Budig's spokeswoman, said he would not comment.

Ads tout program

University and medical center officials refused to close the heart transplant program because colleagues in the liver and kidney transplant programs "felt firmly that any period of inactivity... would be harmful to our [other] transplant programs," the medical staff chief said in a June 1994 memo to Moran.

So concerned were medical center officials with the heart transplant program's image that in November 1994, six months after the center began refusing every heart offer, the university started running radio ads touting its program.

"Our transplant programs for the heart, liver, kidney and bone marrow continue to transform lives," the ad's narrator said as a heart beat in the background. "Place your trust in the area's largest medical university... KU Medical Center. Our doctors teach the other doctors."

By that time, Adrienne Hart was dead. So were patients Richard Miller, 61, of Topeka, Kan., and Robert J. Weingart, 44, of Kansas City.

And Lloyd Croft, 55, a carpenter who had been waiting for a new heart since 1991, was still inching his way up the waiting list. Or so he thought.

After being listed for three years, Croft said he was told by a doctor in 1994 that he wouldn't need a heart transplant immediately and would be placed on "standby," meaning he could be reactivated on the list if his condition worsened. He remained in that status until the scandal broke. He is now a patient at another hospital.

"You're under these professional people's hands, and you're trusting these people," Croft said. "They've got your life literally in their hands, and they backstab you for a couple of dollars."

Auditors found that Croft and 13 other people who were on the waiting list between May 1994 and April 1995 were billed by the medical center for more than \$418,000 in fees not covered by insurance.

UNOS didn't blow whistle

Records show that UNOS, the nonprofit contractor that develops voluntary policies for the University of Kansas Medical Center and other member transplant institutions, was aware early on that the medical center was not doing heart transplants.

Moran, the transplant surgeon who was turning down hearts, told auditors that he called UNOS in May 1994 — when the center stopped doing transplants — to try to get the program inactivated, but was told only hospital administrators had that authority. UNOS officials disputed that, telling auditors they weren't aware of any problems at the center until November 1994.

UNOS was dissuaded from pressuring the university to close the program after several conversations with Dr. George E. Pierce,

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University of Kansas kidney transplant surgeon who served as the medical center's UNOS representative.

Pierce told auditors he came away from the discussions with the understanding that the medical center would be given an "unofficial grace period" to get things straightened out.

He also maintained that "adhering to UNOS guidelines was less important than keeping the heart transplant program active."

UNOS officials also were aware that the medical center had hired Dr. Hamner Hannah, who had not assisted in enough heart transplants to be certified by UNOS, as Moran's replacement. But Pierce told auditors that after initially raising concerns about Hannah's lack of experience, UNOS officials said they "wouldn't object to Dr. Hannah and would, as Dr. Pierce said UNOS implied, 'look the other way.'"

UNOS officials have denied that claim. UNOS legal counsel Cindy H. Sommers declined to answer auditors' questions about whether UNOS allowed Hannah to operate, saying she "didn't want to get into a 'he said, she said.'"

UNOS certification standards, which are voluntary but widely accepted within transplantation, call for heart transplant surgeons to have performed or assisted in at least 20 transplants within three years. Hannah had done just eight, according to the auditors' report.

Hannah, who would not comment for this story, performed his first transplant at the university on March 25, 1995. The patient was Robert W. Trent of Wichita, Kan. Trent, 32, died the same day.

So solicitous was UNOS toward its member institution that after the Star broke the story, former UNOS Executive Director Gene A. Pierce called the medical center's George Pierce (no relation) to assure him that "UNOS didn't blow the whistle" on the medical center, George Pierce told auditors.

The Kansas surgeon went on to quote Gene Pierce of UNOS as telling him that "UNOS had to give in to the reporter's requests under the Freedom of Information Act, and that UNOS stalled on releasing the information for as long as it could," according to the auditors' report.

George Pierce of the medical center declined to comment. Gene Pierce, now retired and living in a Richmond, Va., suburb, said he didn't recall making such comments to the Kansas surgeon.

"I don't recall it exactly like George said, but I trust George so it could have been a misinterpretation or something like that, I'm really not sure," Gene Pierce said. "But we have never tried to stonewall anybody, not while I was there, and if it appeared that way it was for another reason. It certainly was not just stonewalling to stonewall."

Walter K. Graham, who was Gene Pierce's top assistant and succeeded him in 1995 as UNOS' executive director, said UNOS was not aware of the full scope of the problems at the university until after the story broke. But even if UNOS knew that patients were being deceived, Graham said UNOS had no legal authority to intercede.

That has changed under a contract UNOS and the government signed Dec. 30. The contract includes a new clause that requires

UNOS to monitor, investigate and report to the government any incident that "jeopardizes the health of waiting-list patients or transplant recipients."

Graham said UNOS was not in a position to do anything about the Kansas City scandal under the previous contract. He said that responsibility belonged to the hospital.

"Those are issues of fraud, they're issues of malpractice, they're issues that UNOS can not ever get involved in," he added. "We're not ever going to get involved in something like that. That's very much a local legal issue."

'Fear of public opinion'

The University of Kansas scandal also caught the attention of HHS' Division of Organ Transplantation, the agency that regulates UNOS. Director Judith B. Braslow asked UNOS to do a computer run of all times hearts were turned down at the nation's 167 heart transplant centers for the last seven months of 1994. The report showed that 28 centers had turned down for nonmedical reasons 20 percent or more of the heart offers made to them.

And that is where the government's inquiry stopped. Not one of the centers with the high turn-down rates was audited, not one was even contacted, Braslow acknowledged.

"What I was interested in primarily was putting in place a system so that the same thing wouldn't happen a second time," she said. "What's done is done. The Kansas situation had come to light and I thought our role should be to ensure that this didn't happen again. And so we asked that it be referred to the [UNOS] membership and professional standards committee, which it was."

The issue was not addressed by

the UNOS committee until last June, when members voted to begin sending letters of inquiry to any program that turned down 10 consecutive organ offers. As for the sticky issue of what to tell patients, the committee decided that "inactive" programs should inform their patients.

But the committee never decided how long a center could go without performing transplants before being considered inactive, nor did it decide what to do about programs that were turning down large numbers of organs for non-medical reasons and not telling their patients.

UNOS President Dr. James F. Burdick said those issues were "under careful study to determine what might be done to correct them."

"To say that UNOS was at fault there is incorrect," said Burdick, a transplant surgeon at Johns Hopkins Medical Center in Baltimore. "UNOS has done quite a bit in a general way. . . . UNOS doesn't take legal action against transplant centers. In fact, UNOS really doesn't have the power to cause any actual concrete negative impact."

"UNOS' punishment is really fear of public opinion of what might happen if they're not compliant."

From Moran's perspective, there has been no real punishment of the people who were responsible for what went wrong at the University of Kansas Medical Center. As a result, he doesn't foresee being a heart transplant surgeon again.

"Let me tell you: This is a dirty business," said Moran, now a cardiothoracic surgeon at Pitt County Memorial Hospital in Greenville, N.C. "I don't do transplants and I have no interest in ever being involved in transplantation again. It would have to change."

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A CHRONOLOGY OF THE UNIVERSITY OF KANSAS MEDICAL CENTER'S HEART TRANSPLANT PROGRAM

THE PROGRAM

SURGEON SUSPENDED

April 13, 1994 — Dr. Jan F. Moran, one of two heart transplant surgeons at the University of Kansas Medical Center, is suspended as chairman of the Department of Cardiothoracic Surgery after he refuses to do transplants due to inadequate nursing staff.

PATIENTS MISLED

June 24, 1994 — Moran's lawyer sends a letter to university Chancellor Gene A. Budig and others, informing them that the hospital has been "misleading" heart transplant patients by refusing to tell them the program is inactive.



BUDIG RESIGNS

Aug. 1, 1994 — Budig resigns as chancellor to become president of baseball's American League.

SURGEON QUILTS

Nov. 1, 1994 — Dr. Clay Beggerly resigns, leaving Moran as the hospital's only UNOS-certified heart transplant surgeon. Moran informs the United Network for Organ Sharing, the national organ donor databank, that neither he nor Beggerly will be performing heart transplants.

NOT ENOUGH EXPERIENCE

Jan. 24, 1995 — UNOS informs the hospital that Hannah does not meet minimum experience requirements because he has only done eight transplants.

NOT UP TO STANDARDS

Feb. 21, 1995 — A UNOS committee again informs the hospital that Hannah does not meet certification criteria.

PROGRAM SHUTS DOWN

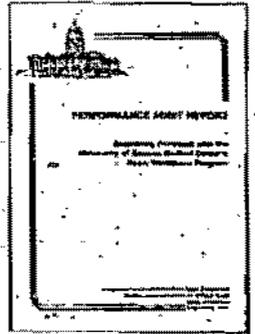
April 7, 1995 — The hospital agrees to "voluntarily" close its heart transplant program.

MORE TURNDOWNS

May 31, 1995 — A UNOS report finds that numerous other heart transplant centers have high non-medical turndown rates. None of the centers are audited or questioned about the findings.

REVEALING REPORT

May 7, 1995 — The Kansas City Star reports that between May 1994 and March 1995, the hospital performed no heart transplants, turning down all 50 heart offers to its patients.



A CHARGE OF DECEPTION

Sept. 26, 1995 — A state audit of the hospital's heart transplant program finds that doctors and nurses deceived patients by failing to inform them that the program was inactive.

NO SHUTDOWN

Dec. 1, 1994 — Dr. George E. Pierce, the hospital's UNOS representative, informs UNOS that the university does not want to close the heart transplant program and that it has hired Dr. Hamner Hannah to replace Moran.

INTERVIEW REQUESTED

March 3, 1995 — Hospital officials request an interview with UNOS to discuss Hannah's qualifications.

1994



DIES June 30, 1994 — Emery D. Day, a machinist and welder from Topeka, Kan., dies after receiving a heart transplant on May 1, 1994. He is the last person to be transplanted at the hospital until March 25, 1995.

DIES Aug. 8, 1994 — Adrienne Hart, 16, of St. Joseph, Mo., dies while being evaluated for a heart transplant.

DIES Aug. 17, 1994 — Richard Müller, 61, of Topeka, dies while waiting for a heart.

DIES July 7, 1994 — Robert J. Weingart, 44, of Kansas City, Kan., dies while being evaluated for a heart transplant.

THE PATIENTS

1995



Hart

DIES Dec. 15, 1994 — Winifred E. Hesse, 49, of Topeka, dies while waiting for a donor heart.

DIES Feb. 4, 1995 — Gary K. Bergmann, 61, of Pleasant Hill, Mo., dies. His widow's affidavit says his cardiologist told the Bergmanns in April 1994 that Bergmann would be added to the waiting list. Bergmann dies never realizing he was not on the list.

DIES Feb. 15, 1995 — Robert M. Arsiaga, 47, of Kansas City, Mo., dies while waiting for a heart.

DIES March 23, 1995 — Raymond Price, 20, of King City, Mo., dies after being sent home to wait for a new heart. He was never on the waiting list.

DIES March 25, 1995 — Robert W. Trent, 32, of Wichita, Kan., dies a few hours after Hannah, whose UNOS certification is still unresolved, performs a heart transplant on him.



Price

1996



SETTLEMENT FOR 15 PATIENTS
Aug. 29, 1996 — The hospital and two medical foundations agree to pay \$265,000 in restitution, penalties and fees. The settlement calls for payments of \$11,000 to 15 patients or their survivors.

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TRANSPLANTING LIFE

THE TRIUMPHS, THE TRAPS, THE TRAGEDIES

Sunday: When Linda Robinson's 37-year-old heart began to fail, forcing her to take up residence on the ninth floor of the Cleveland Clinic last May, she faced the transplant paradox: For her to live, someone had to die. For Linda and her family, the wait for a new heart was a frightening reminder of the fragility of life and a close-up look at one of modern medicine's most astonishing frontiers.

Yesterday: U.S. transplant centers turn down many of the scarce donor organs they are offered. Although most refusals are based on medical judgments, hundreds of offers of hearts, livers and other organs are refused due to the unavailability of surgeons or because the programs are too busy. Patients are never told of the refusals because the agencies charged with overseeing the distribution of donor organs refuse to make that information public.

Tomorrow: If you need a new kidney, the median waiting time for a transplant ranges from less than two months at a hospital in Fort Worth, Texas, to 858 days at a medical center in Hershey, Pa. The median wait for a liver transplant is 18 days at a medical center in New Orleans but 648 days for the Boston hospitals that are served by the New England Organ Bank. In the continuing debate over equity in organ transplantation, no issue strikes more at the heart of the dispute than the gross disparity in waiting times.

Thursday: On average, patients who receive organ transplants at low-volume centers are more likely to die within the first year than those who undergo transplants at high-volume centers. Few patients are aware that they can significantly increase their chances of survival by going to a transplant center that does the risky surgery more frequently.



PHAEDRA SINGELIS/PLAIN DEALER PHOTOGRAPHER

Ralph and Donna Vairo, who live near Santa Cruz, Calif., have been told that Ralph Vairo could die waiting for a new liver unless he transfers from the University of California at San Francisco to a transplant center with a shorter waiting time.

Doctor to patient: Get out of here or you'll die waiting

Fourth of five articles

By JOAN MAZZOLINI,
TED WENDLING
and DAVE DAVIS
PLAIN DEALER REPORTERS

SAN FRANCISCO — Liver surgeon John Roberts is doing the unthinkable — telling some of his most seriously ill patients that if they don't go elsewhere, they will die waiting on his hospital's transplant list.

And if Ralph Vairo, a 60-year-old former painting contractor who lives near Santa Cruz, makes it to 61, he may owe his life to Roberts' decision.

Vairo has a cancerous tumor in his liver that will spread throughout his body and kill him if he doesn't receive a new liver soon.

His insurance company, Kaiser Permanente, contracts with the University of California at San Francisco to do liver transplants. So Vairo's doctor dutifully referred him there to see if he was a candidate for transplantation.

But when Roberts saw him in October, Vairo recalled the surgeon saying, "You need a liver. It's too long of a wait here. I'm going to recommend to your doctor and insurance company that you go someplace else."

Transplant patients are keenly aware that they may die while waiting their turn for an organ. What many don't know is that, due to wide disparities in donation rates and attempts by organ banks and transplant centers to keep locally donated organs, the waiting time for an organ varies dramatically depending on where they are treated.

Hospital administrators are not happy about Roberts telling patients to go elsewhere, he said. "The issue has to do with the fact that you're telling patients to go to other centers, not that we will do fewer transplants. We won't."

But his overriding concern is that the median waiting time for a liver in San Francisco in 1995 was 473 days — the longest in the state and third longest in the country. In contrast, the median wait at one center in Los Angeles was just 87 days.

And the difference of 386 days, for seriously ill patients such as Vairo, may be the difference between life and death.

Vairo and his wife, Donna, said they were shocked by the differences in waiting times. Even the doctor who referred him to San Francisco had no idea about the long wait.

Most transplant doctors don't

provide patients with information about waiting times. Roberts and others say the discrepancy in waiting times is irrefutable evidence that the nation's organ allocation system remains unfair and that not everyone has an equal chance of getting a donated organ.

And the disparity in waiting times doesn't pertain just to livers, but to all organs. For example, patients in Cincinnati had a median wait of about six months for a heart in 1995, while patients in nearby Fort Wayne, Ind., waited about 1½ years.

Numbers like these pose a dilemma for the United Network for Organ Sharing, the nonprofit organization that tracks waiting times and holds a government contract to match donated organs with waiting patients. A major function of UNOS' Organ Procurement and Transplantation Network is to establish an equitable and medically sound organ distribution system.

"In some parts of the Southeast, there are waiting times that are two to three weeks long, and then you go to the Northeast in Boston, where the waiting times are over a year," said Dr. John J. Fung, director of the liver transplant program at the University of Pittsburgh.

SEE LIST 16



Waiting times differ around nation

LIST FROM 1-A

"If anything is going to tell the public that, hey, something doesn't smell right, it's that kind of disparity," Fung said. "It jumps out at you."

Dr. James F. Burdick, UNOS president, believes that attempts by transplant centers and organ banks to control locally harvested organs have hurt the national, voluntary allocation policy.

Burdick, a transplant surgeon at Johns Hopkins Hospital in Baltimore, said that sense of ownership "impedes the development of an equitable and national system for distributing organs."

Many doctors and transplant professionals say, however, that the quest for true equity may be unobtainable because any actions UNOS takes will still involve the rationing of scarce organs, and thousands of people will continue to die on waiting lists.

They also note that UNOS is an agency that rules by consensus, and that UNOS' 39-member board and more than 400 member institutions make consensus difficult.

Dirty laundry

In an anonymous survey done by UNOS last fall, most UNOS members involved in liver transplantation said they believed data on waiting times and deaths on the waiting list should be available to transplant patients and their referring doctors.

Although government pressure forced UNOS to begin publishing center-specific mortality data, UNOS officials and a small group of doctors have kept center-specific waiting time data from being made public, claiming that the data are "meaningless" because centers are listing patients at different stages of their illnesses.

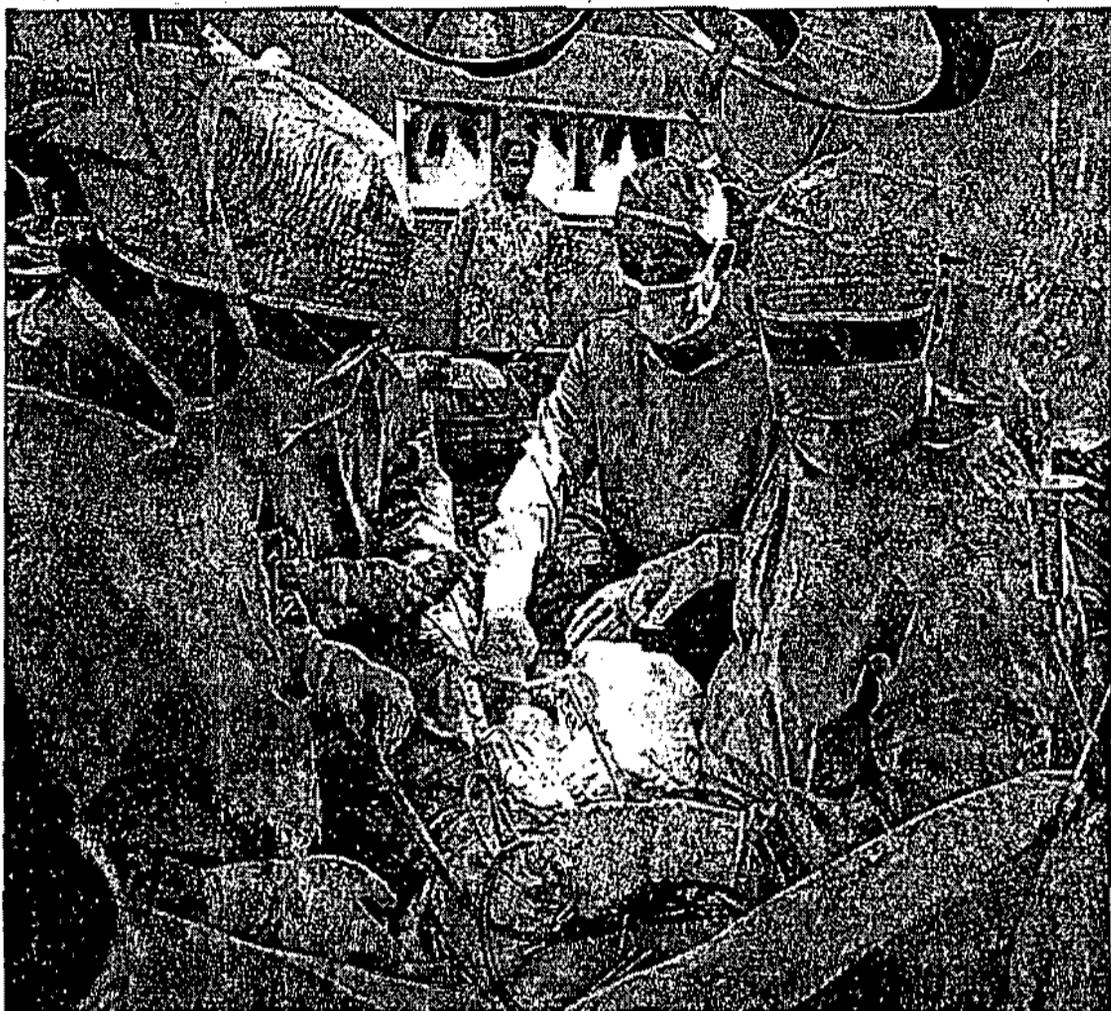
One liver transplant official

TRANSPLANT FACTS

As of December 1996, 889 patients were waiting for organs at northeast Ohio hospitals.

For a kidney	675
For a heart	112
For a liver	112
For a pancreas	8
For a lung	37
For a heart/lung	3
For a kidney/pancreas	52

SOURCE: LifeBanc



ELIZABETH MALBY / PLAIN DEALER PHOTOGRAPHER

A donor's chest is opened as surgeons prepare to remove organs for transplantation.

who responded to the survey opposed releasing the waiting time data because to do so "would condemn the current UNOS allocation system and make its gross inequities public knowledge. I do not feel that we need to air our dirty laundry. Let's just fix it."

In November, the UNOS board of directors voted to release a report in 1997 on waiting times. But instead of publishing waiting times by center, which would help patients decide where to go, the board decided to release a report on waiting times by organ bank, which serve regions of the country.

"I'm afraid that if patients take a look at the report on the [organ banks], it still won't help them make a decision about what transplant center to go to," said Phyllis G. Weber, executive director of the California Transplant Donor Network in San Francisco and a member of the UNOS board.

Weber isn't alone in her concern that organ bank waiting time will be of little help. Weber and some other board members also were unaware that UNOS has center-specific waiting time reports, which The Plain Dealer obtained under the Freedom of Information Act.

If transplant center officials were to explain to patients that waiting times vary greatly in different parts of the country, they also would have to explain that there is no true national waiting list for patients needing a lifesaving organ transplant, something that many patients do not understand.

Many patients believe there is one long waiting list for each organ. They believe they have a place on that list, and that they move up as they get sicker or with each transplant that is performed.

They are wrong. Instead, what's in place is more like a net-

work of smaller statewide or communitywide lists. And how long patients wait for organs depends greatly on where they live and how well their local organ banks do at persuading people to donate.

While UNOS has established a "policy" on how to allocate organs, it's not followed throughout the country. The voluntary policy has been revised by sharing agreements and variances granted by UNOS that cover about 16 states, including Ohio.

Ohio, like some other states and regions, has a sharing agreement that attempts to keep organs in-state, regardless of whether more seriously ill patients need them elsewhere.

Few transplant officials advocate a national system that would establish a single national waiting list that would ship organs cross-country to the next waiting patient.

SEE SYSTEM/7-A



CRITICALLY IMPORTANT

New policy weighed for allocations

SYSTEM FROM 6-A

Instead, many doctors believe that waiting times could be equalized and equity could be achieved by sharing organs within several "super regions" that would account for differences in population, donor patterns and rates of disease.

The liver wars

The disparity in waiting times has been especially hotly debated within the liver transplant community, where since 1991 UNOS has used an allocation system that is different than for any other organ. It is a system, its critics say, that allocates organs to transplant centers, not patients.

The decision by UNOS to allocate livers locally instead of giving them to the sickest patients has been a major incentive for hospitals to set up liver transplant programs, now a more than \$300 million-a-year industry. The new allocation system provides organs to newly established programs that otherwise wouldn't get them because they generally have small waiting lists and few seriously ill patients.

It also provides a source of local organs for patients whose problems have not yet become life-threatening and who are expected to have a better chance of surviving a transplant.

In 1989, two years before the policy was implemented, there were 79 liver transplant centers, according to UNOS. Two years after the change, in 1993, there were 112 centers, a 29 percent increase.

The allocation change had serious side effects for large centers. Those centers could not now draw many organs from outside their local areas, despite drawing patients nationwide. With the number of patients who could benefit from transplantation increasing, the effect was to cut off organs for many critically ill patients, creating hopelessly long waiting lists.

At the same time, the waiting-time disparity grew, which in 1994 and 1995 ranged from 18 days at Tulane Medical Center Hospital in New Orleans to an average of 648 days at the four liver transplant centers in Boston.

"The control of donor organs by transplant centers and their professionals is driven by financial considerations, not by what is fair and equitable for their patients,"

Dr. Jeffrey S. Crippin, a liver transplant surgeon at Baylor University Medical Center in Dallas, testified at a UNOS hearing in September.

"In a situation of unmet need, with patients dying daily for the want of a donor liver, what is fair to all patients is to have approximately the same opportunity of receiving a donor liver," Crippin said.

At the hearing, a move by UNOS to equalize waiting times by creating wider geographic regions to match organs for the sickest patients was tabled after small- and medium-sized centers, concerned about controlling local organs, opposed it.

TRANSPLANT FACTS

Year	Annual number of heart transplants in the U.S.
1989	1,705
1990	2,108
1991	2,125
1992	2,171
1993	2,297
1994	2,340
1995	2,434
1996 (est.)	2,507

SOURCE: Millman & Robertson Inc., Brookfield, Wis., consulting actuaries

Nearly 80 percent of UNOS' 118 liver transplant center members fall into the "small" and medium-sized group — those that do fewer than 50 transplants a year. They dominate UNOS' committees, which make policy recommendations to the board.

One of the more outspoken critics of the UNOS proposal was Dr. John C. McDonald, chairman of the department of surgery at the Louisiana State University School of Medicine in Shreveport.

"This policy will divert livers from needy ... patients in Louisiana to wealthy patients in other states," said McDonald, who added that state residents are guaranteed access to transplantation under state law, regardless of their ability to pay. "It will divert livers to centers which have taken on more patients than they can serve."

The inability of UNOS to resolve the controversy internally prompted U.S. Department of Health and Human Services Secretary Donna Shalala, whose agency has allowed transplant centers to largely regulate themselves, to intervene.

Shalala called three days of public hearings on the issue in December and said she would determine, within three months, how best to allocate scarce donor organs. In a letter outlining her reasons for the hearing, Shalala said a federal decision on liver allocation would eliminate the public perception that UNOS isn't able to change the current policy because the self-interest of its members stands in the way.

"Any decision, whether it be a new policy or a reaffirmation of the current one, is certain to draw intense public and congressional interest," Shalala wrote. She added, "I am disappointed that the allocation policies to date have provoked considerable unresolved controversy within the transplant community."

No standardized listing

Even though livers are allocated according to a different system, the variance in median waiting times for other major organs is about as great, according to UNOS data.

For hearts, it stretched from a low of 28 days at Medical City Dallas Hospital (for adults) to a high of 815 days at the University of Minnesota Hospital in Minneapolis. For kidneys, it ranged from 54 days at Harris Methodist Hospital in Fort Worth, Texas, to 858 days at Milton S. Hershey Medical Center in Hershey, Pa.

Transplant doctors point out that patients' waiting times are based on many factors, including blood type, height, weight, and the stage of illness at which the patient is put on the waiting list. Those and other factors make one person's wait longer or shorter than another's.

"You've got to look at it in the light of the listing criteria — that's a large part of the problem," said Dr. J. Michael Henderson, director of the Cleveland Clinic's liver transplant program. "The nation does not have a standardized listing criteria. You can get on a list in one part of the country a lot earlier than other parts of the country."

In November, the UNOS board voted to establish standardized

listing this year, modeled in part after Ohio's system.

But for the last 12 years in Ohio, patients have been listed at the same stages of their disease and the waiting times for heart, liver and pancreas transplants at the centers here still vary greatly.

Henderson said that was because "you still have local priority" and because some programs are more aggressive than others about transplanting so-called "marginal" organs into their sickest patients.

"Waiting time is not the gold standard of equity," said Dr. Ronald M. Ferguson, a liver transplant surgeon at Ohio State University Hospital. "If you have to few organs and too many patients, somebody is going to get the sticky end of the Popsicle stick."

Aside from the ethical arguments for telling patients about the differences in waiting times, Roberts, the San Francisco surgeon, said that doctors who are worried about being sued should have a selfish motive for disclosing the differences.

"If you don't open up the issue the next thing that happens is the family says, 'Why didn't you tell me my mother could go and get transplanted someplace else? We'll start being asked, and rightly so, 'Is the issue money doctor?'"

Roberts and others say the same is true for insurance companies, which could be asked whether they are directing patients to specific centers — some with long waiting times — because the centers are giving them big price breaks.

For Vairo, the retired painting contractor, the insurance issue is being worked out. In addition to the University of California at San Francisco, Kaiser contracts with four other hospitals for adult liver transplantation, including the University of Alabama at Birmingham Hospital.

In 1995, the median waiting time at UAB was 88 days, more than a year shorter than his expected wait in San Francisco.

Vairo heard recently, after visiting the Alabama center with his wife, that he had been accepted and placed on the list in Birmingham.

Kaiser agreed to pay for the trip, as well as his expenses to move there for several months to wait for a liver.

"I'm lucky because it's very small," Vairo said of his cancer. "But it could spread, and then they wouldn't do anything."

"My doctor said, 'They'd open you up and if they see that it's spread, they close you up and you just wait.'"

"I'm not ready to check out. I've got too much to live for."

FOR YOUR INFORMATION

Internet newsgroup on transplants

Information about transplants is available on the Internet.

If you have access to electronic mail, the transplant newsgroup provides a forum for organ transplant recipients and donors, their families and members of the transplant community.

Recent topics include waiting

times, transplant costs, the negative side effects of anti-rejection drugs and media coverage of transplantation.

To participate, send an e-mail message that states "SUB TRNSPLNT (Your full name) to listserv@wvumc.wustl.edu."

VERY IMPORTANT

Staying close to home

Challenging the odds, a liver transplant patient shuns a shorter wait to be at home

By JOAN MAZZOLINI
PLANNING A LIVER TRANSPLANT

OAKLAND, Calif. — Like many patients awaiting an organ transplant, Karl Lindinger didn't know about the big differences in waiting times among transplant centers.

But after 18 months on Stanford University Hospital's liver transplant list, Lindinger now knows that where you are treated can have as much to do with when you get a transplant as how sick you are.

Lindinger, 42, already has waited twice as long as patients at the University of California at Los Angeles. And his two separate insurance policies would allow him to go to out-of-state centers with even shorter waits.

But Lindinger said he feels comfortable being closer to home and with a staff he has gotten to know at Stanford.

"My doctors here are extremely good, and I feel very confident about them," Lindinger said when asked why he doesn't look into going to a cen-

ter with a shorter waiting time. "I don't want to change it.

"My gastroenterologist is a doll. He's so concerned about patient care before the money issue comes in, which is really nice to have."

Lindinger is a native of Austria. He lives in a low-rent apartment he moved into after he became too sick to continue his hotel manager's job.

He has no family nearby, but many friends. Melba Ohi, a 74-year-old friend from Illinois who had planned to help him after the transplant, came to Oakland early because Lindinger's health had deteriorated.

Lindinger's liver was damaged by cirrhosis. He said his doctors recently told him that the cirrhosis was caused by a non-viral type of hepatitis.

His liver is three times its normal size. He takes megadoses of medication that leave him barely conscious, and internal bleeding and brain swelling have put him in comas and in and out of the hospital.

But if a liver becomes available in Sacramento, someone who is well enough to be home and working there could get the organ before Lindinger, who lives about 1½ hours away.

When Lindinger went on the waiting list in August 1995 at Stanford University Hospital in Palo Alto, Calif., his doctors told him he would live less than two

years without a transplant. And they told him it would be about a year before he got a new liver.

After the year came and went, Lindinger said the doctors told him the wait would be another six months. Now Lindinger is worried that his time is running out.

"My doctor said there's noth-

ing more they can do for me, that I might go into another coma and that'll be that," Lindinger said. "Unless I get the transplant."

Stanford officials have told him they are doing everything they can to find him a liver. And that has won Lindinger's trust and kept him from going elsewhere.

Lindinger is like many — if not

most — patients, say officials in the transplant field. Overwhelmed by anxiety and the need to be close to friends and family at home, many patients put their faith in their local hospitals and doctors. They don't ask many questions, afraid of the answers.

"I don't want to change," he said. "It's a gamble."

State's policy: Ohio organs for Ohioans first

By JOAN MAZZOLINI

If you die in Ohio, Ohio wants your organs.
Preferably, for another Ohioan.
In what may be the ultimate act of provincialism, the architects of the national organ-distribution network have created a system in which local ownership rules.

Say, for instance, that a donor heart becomes available in Toledo, but isn't a match for a patient at the Medical College of Ohio, the only heart transplant center in northwest Ohio. Under rules adopted by the Ohio Solid Organ Transplant Consortium, the next step would be to look for the best match for the sickest patient waiting at one of Ohio's three other heart transplant centers -- in Cleveland or Columbus, which are, respectively, 97 and 121 miles from Toledo, or in Cincinnati, 184 miles away.

That's true even if the nearest matching patient for the Toledo heart is sicker than the Ohio patients and is dying just 53 miles away in Detroit.

"I think that's very reasonable," said Dr. Thomas E. Walsh, a consortium board member and director of the heart transplant program at the Medical College of Ohio. "You have to draw boundaries somehow, and that turns out to be the way the boundaries are drawn. . . . I think it's been very fair."

Ohio is one of about 16 states, regions and metropolitan areas around the country that have variances or sharing agreements. They allow states, transplant centers and organ banks to circumvent the national organ allocation policy.

That policy was established by the United Network for Organ Sharing under the auspices of Congress. Congress passed the National Organ Transplant Act in 1984 and the Transplant Amendments Act in 1990, which required the development of an "equitable" organ distribution plan that would be carried out "in accord with a national system."

Despite that edict, investiga-

tions by the U.S. Department of Health and Human Services' office of the inspector general in 1991 and the General Accounting Office in 1993 both found that in addition to the huge differences in the length of time patients waited for organs at different centers, there was no true national allocation system.

The investigations found that as the number of waiting patients, transplant centers and the competition for scarce donor organs grew, so had the transplant facilities' desire to control organs from local or state residents.

"It's extremely alarming when in fact we don't have a national system at all, but instead these arbitrary geographic boundaries, which preclude a national system," said Charles E. Fiske, co-director of the National Transplant Action Committee, a patient-advocacy group of transplant recipients and their families. "These variances protect the best interest of the transplant center rather than the best interest of the patient."

UNOS, which since 1986 has held the government contract for matching waiting patients with donor organs, has approved these variances and sharing agreements.

Ohio's system was set up about 12 years ago. It is considered a model in the country because, in addition to sharing organs for critically ill patients across the state, groups of doctors from the Ohio centers, under the auspices of the Ohio Solid Organ Transplant Consortium, approve patients who are put on transplant waiting lists at the Ohio hospitals.

But, like sharing agreements in New York, Tennessee, Georgia and some other states, Ohio's strives to keep most organs within state lines, even though patients commonly cross those boundaries when seeking medical care, often at the insistence of their insurers.

"It's another exception after another exception," Fiske said. "This flies in the face of treating the sickest patient first."



WAITING TIMES

The lists below rank the nation's transplant centers according to the median number of days patients waited for a transplant. The "Patients added" column is the number of people who joined the waiting list during the year and the "Median waiting time" is the mid-point in days those patients waited for a transplant. The data below covers the most recent year for which a median waiting time could be calculated, either 1994 or 1995. NA means the waiting time could not be calculated, because fewer than 10 people joined the waiting list and/or the center did not perform enough transplants for the waiting time to be statistically significant.

HEART

Ten shortest		
Hospital, City, State	Patients added	Median waiting time
1 Henretta Egleston, Atlanta, GA	23	27
2 Medical City Dallas, Dallas, TX	25	28
3 St. Louis Children's, St. Louis, MO	28	38
4 Mercy, Des Moines, IA	12	48
5 Jackson Memorial, Miami, FL	44	51
6 Loma Linda University, Loma Linda, CA	52	52
7 Methodist, Houston, TX	20	53
8 UCSD, San Diego, CA	17	57
9 Cedars-Sinai, Los Angeles, CA	33	58
10 St. Christopher, Philadelphia, PA	18	59
Ten longest		
99 Donald N. Sharp Memorial, San Diego, CA	27	408
100 Baptist, Oklahoma City, OK	36	428
101 Loyola University, Maywood, IL	33	430
102 Presbyterian-University, Pittsburgh, PA	82	436
103 Lutheran, Fort Wayne, IN	22	544
104 St. Mary's, Rochester, MN	41	594
105 Emory University, Atlanta, GA	72	665
106 Allegheny General, Pittsburgh, PA	20	740
107 Willis Knighton, Shreveport, LA	82	768
108 University of Minnesota, Minneapolis, MN	31	815
Others in Ohio		
32 University of Cincinnati, Cincinnati	33	122
41 Cleveland Clinic, Cleveland Children's, Cincinnati	128	149
Medical College of Ohio, Toledo	1	NA
Ohio State University, Columbus	22	NA
Children's, Columbus	20	NA
	0	NA

KIDNEY

Ten shortest		
Hospital, City, State	Patients added	Median waiting time
1 Harris Methodist, Fort Worth, TX	58	54
2 Presbyterian-University, Pittsburgh, PA	12	79
3 Southwest Florida, Fort Myers, FL	37	114
4 Henretta Egleston, Atlanta, GA	10	144
5 Oregon Health Sciences, Portland, OR	137	147
6 University, Lubbock, TX	13	154
7 Methodist, Lubbock, TX	14	162.5
8 Jackson Memorial, Miami, FL	140	166
9 St. John, Tulsa, OK	11	170
10 University of Cincinnati, Cincinnati, OH	42	174
Ten longest		
109 Virginia Mason, Seattle, WA	116	750
110 Francis Scott Key, Baltimore, MD	44	761
111 Parkland Memorial, Dallas, TX	74	763
112 University of North Carolina, Chapel Hill, NC	59	810
113 Mount Sinai, New York, NY	101	812
114 University of Pennsylvania, Philadelphia, PA	163	822
115 Northwestern Memorial, Chicago, IL	186	828
116 Lehigh Valley, Allentown, PA	38	838
117 William Beaumont, Royal Oak, MI	106	850
118 Milton Hershey, Hershey, PA	111	858

Others in Ohio			
14	Miami Valley, Dayton	28	204
19	Medical College, Toledo	46	218
25	Christ, Cincinnati	38	260
82	Ohio State University, Columbus	276	431
	Akron City, Akron	28	NA
	Children's, Cincinnati	9	NA
	Children's, Columbus	1	NA
	Children's, Akron	1	NA
	Cleveland Clinic, Cleveland	142	NA
	University Hospitals, Cleveland	126	NA
	St. Elizabeth, Youngstown	44	NA

LIVER

Ten shortest			
Hospital, City, State	Patients added	Median waiting time	
1	Tulane, New Orleans, LA	18	18
2	University of Kansas, Kansas City, KS	30	21
3	Jewish, Louisville, KY	47	38
4	University, Newark, NJ	50	40
5	Children's, Dallas, TX	21	42
6	University of Wisconsin, Madison, WI	101	54
7	Jackson Memorial, Miami, FL	285	64
8	Vanderbilt University, Nashville, TN	41	71
9	Henrietta Egleston, Atlanta, GA	12	77
10	Froedtert Memorial Lutheran, Milwaukee, WI	31	80
Ten longest			
75	Methodist, Indianapolis, IN	34	385
76	Cleveland Clinic, Cleveland, OH	97	394
77	University of Michigan, Ann Arbor, MI	162	401
78	University, Denver, CO	113	405
79	Rush-Presbyterian/St. Luke's, Chicago, IL	186	423
80	University, Cleveland, OH	51	445
81	California Pacific, San Francisco, CA	217	473
82	University of Maryland, Baltimore, MD	27	518
83	Johns Hopkins, Baltimore, MD	185	583
84	New England Organ Bank Centers*	307	648
Others in Ohio			
20	Ohio State University, Columbus	48	104
28	Children's, Cincinnati	15	132
58	University of Cincinnati, Cincinnati	43	258
	Children's, Columbus	0	NA

*Includes combined figures for Children's, Boston; New England Deaconess, Boston; Massachusetts General, Boston; and New England Medical Center, Boston.

LUNG

Ten shortest			
Hospital, City, State	Patients added	Median waiting time	
1	Ochsner, New Orleans, LA	12	43
2	Children's, Philadelphia, PA	18	62
3	University of Alabama, Birmingham, AL	32	77
4	Vanderbilt University, Nashville, TN	17	80
5	Medical University, Charleston, SC	12	99
6	University, Lexington, KY	38	114
7	Shands, Gainesville, FL	30	124
8	Methodist, Houston, TX	22	128
9	University of CA Davis, Sacramento, CA	12	129.5
10	Temple University, Philadelphia, PA	16	148
Ten longest			
28	St. Louis Children's, St. Louis, MO	41	408
29	UCLA, Los Angeles, CA	37	417
30	Duke University, Durham, NC	60	449
31	University of Pennsylvania, Philadelphia, PA	73	469
32	University of Virginia, Charlottesville, VA	26	528
33	Methodist, Indianapolis, IN	25	598
34	Barnes, St. Louis, MO	125	690
35	University of North Carolina, Chapel Hill, NC	50	762
36	University of Michigan, Ann Arbor, MI	44	793
37	Presbyterian, New York, NY	73	801
Others in Ohio			
22	Cleveland Clinic, Cleveland	40	332

SOURCE: United Network for Organ Sharing

PLAIN DEALER

TRANSPLANTING LIFE

THE TRIUMPHS, THE TRAPS, THE TRAGEDIES

Sunday: When Linda Robinson's 37-year-old heart began to fail, forcing her to take up residence on the ninth floor of the Cleveland Clinic last May, she faced the transplant paradox: For her to live, someone had to die. For Linda and her family, the wait for a new heart was a frightening reminder of the fragility of life and a close-up look at one of modern medicine's most astonishing frontiers.

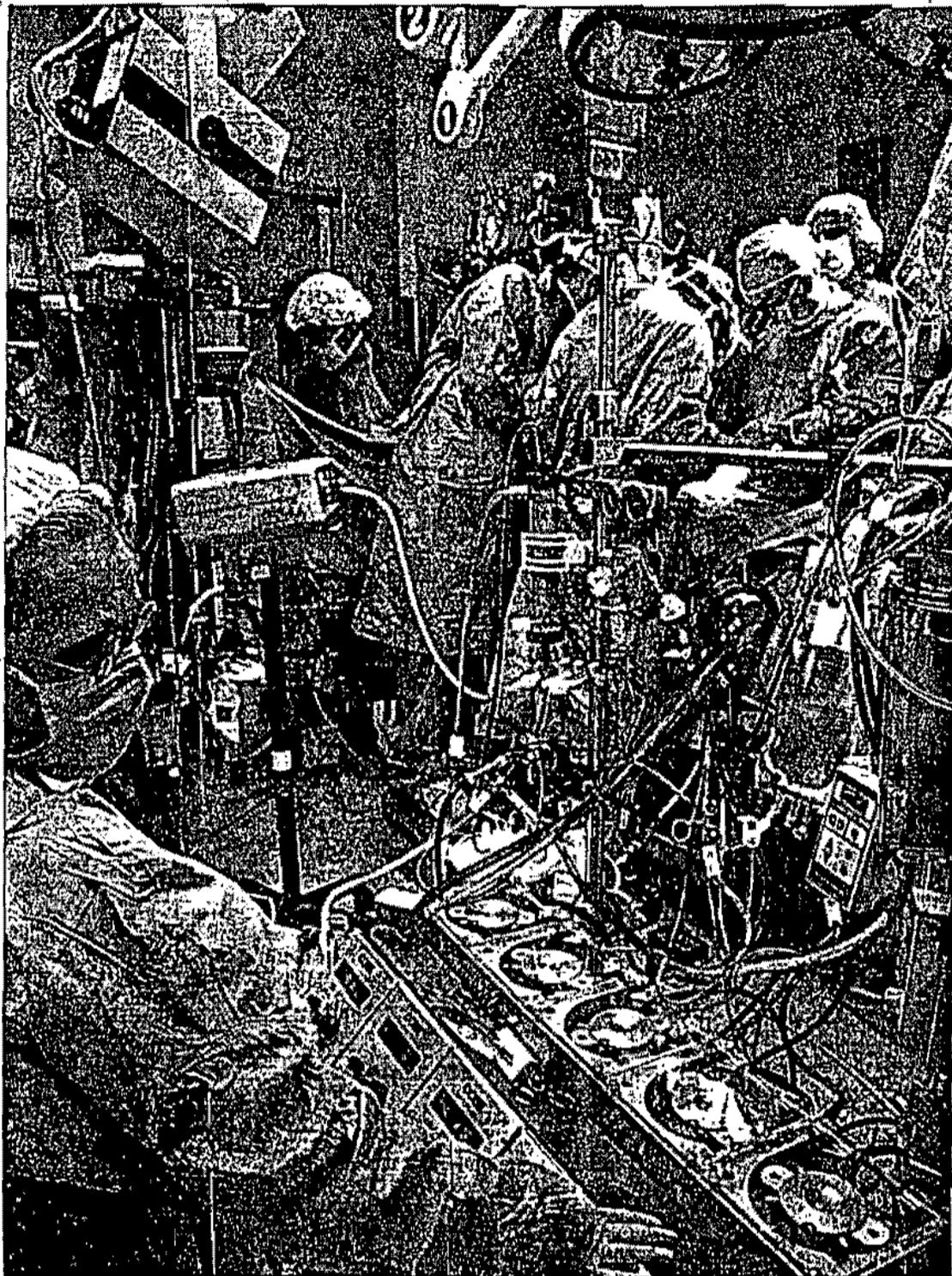
Monday: U.S. transplant centers turn down many of the scarce donor organs they are offered. Although most refusals are based on medical judgments, hundreds of

offers of hearts, livers and other organs are refused due to the unavailability of surgeons or because the programs are too busy. Patients are never told of the refusals because the agencies charged with overseeing the distribution of donor organs refuse to make that information public.

Yesterday: During an 11-month period in 1994 and 1995, the University of Kansas Medical Center placed on its heart transplant waiting list, or evaluated for placement, 38 patients without telling them that they had little chance of actually receiving a transplant because internal

squabbles had shut the program down. As two-state investigations later verified, patients were deceived and university officials failed to act.

Tomorrow: On average, patients who receive organ transplants at low-volume centers are more likely to die within the first year than those who undergo transplants at high-volume centers. Few patients are aware that they can significantly increase their chances of survival by going to a transplant center that does the risky surgery more frequently.



PHAEDRA SINGELIS / PLAIN DEALER PHOTOGRAPHER

The Cleveland Clinic has one of the busiest heart transplant programs in the country. Here, a doctor operates the heart-lung machine, which takes over the functions of those organs during a heart transplant.

Low-volume centers lead in rate of death

Last of five articles

By JOAN MAZZOLINI
DAVE DAVIS
and TED WENDLING

PLAIN DEALER REPORTERS

Patients who receive organ transplants at so-called "low-volume" centers are more likely to die within the first year than those who go to high-volume centers, a Plain Dealer analysis of transplant records shows.

Few patients understand that the number of transplants performed plays a crucial role in keeping surgical teams sharp, or that they can significantly increase their chances of survival by going to transplant centers that do the risky surgery more often.

"Yeah, it would save some lives if those [low-volume] centers ba-

Waiting times, mortality and volume data on all U.S. transplant centers. 8-A

sically stopped doing transplants," said Dr. Jeffrey D. Hosenpud, a heart transplant cardiologist at the Medical College of Wisconsin Hospital in Milwaukee. "And, obviously, that's critically important if you happen to be one of those lives."

Hosenpud co-authored a study that concluded that the risks of mortality at one month and at one year were "substantially higher" at low-volume heart transplant centers, those that perform fewer than nine transplants a year. Such centers accounted for about half of those doing heart transplants in the United States, but they performed only 15 percent of

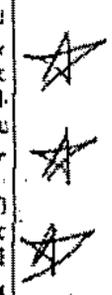
all heart transplants.

The study, which examined the outcomes of 7,893 heart transplants between October 1987 and 1991, was published in the Journal of the American Medical Association in 1994.

Hosenpud also said the number of lives that could be saved by eliminating low-volume heart centers is probably not as great as the number that could be saved by eliminating low-volume liver centers. Liver transplants require greater technical ability on the part of the surgical team.

A study sponsored by the University of Pittsburgh found that if low-volume liver centers or those with higher-than-expected mortality rates were closed, the lives of about 350 transplant patients a year would be saved.

SEE ANALYSIS/9-A



Analysis shows death rate higher at low-volume centers

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ANALYSIS FROM I-A

"There are some small centers that have done well, but not a majority," said Dr. John J. Fung, director of Pittsburgh's liver transplant program. "In fact, 75 percent of the small programs are not good programs."

"We try not to focus on this because we end up polarizing the transplant community. But we believe poorly performing programs should be looked at."

The Plain Dealer analysis of transplant centers was based on 55,990 organ transplants performed from Oct. 1, 1987, to Dec. 31, 1991, the most recent period for which records were available. For each type of organ transplant, roughly half the centers in the country fell into the low-volume category. Low-volume centers accounted for 9,049 organ transplants, or about 16 percent of the total transplants in the analysis.

The analysis showed that the patient death rate during the first year was higher on average for low-volume centers than for high-volume centers. For example:

At low-volume heart transplant centers, those averaging fewer than nine transplants a year, 24 percent of the patients died within a year — an increase of 33 percent over the death rate of 18 percent at high-volume centers.

At low-volume liver transplant centers, those averaging 13 or fewer transplants a year, 32 percent of the patients died within a year — an increase of 28 percent over the death rate of 25 percent at high-volume centers.

And at low-volume pancreas centers, those averaging fewer than six transplants a year, 15 percent of the patients died within a year — an increase of 50 percent over the death rate of 10 percent at high-volume centers.

The mortality rates for the low- and high-volume centers are averages for each group. A particular low-volume center may have a one-year mortality rate that is significantly higher or lower than the low-volume group average, just as any high volume center might differ from the overall high-volume group average.

Experts say patients and their families should know the most recent mortality rates for the centers they are visiting, as well as the median waiting time for the needed organ.

The importance of volume

Transplants are risky even under the best circumstances, and volume is only one predictor of patient mortality. Other factors, such as a patient's overall medical condition or whether it is a first or second transplant, are considered better indicators of whether someone will live a year or longer.

But understanding the effect of volume on outcome can help patients pick the right transplant center and increase their likelihood of surviving.

Even when the data were adjusted to account for differences in the severity of patients' illnesses and the quality of the donor organs hospitals received — to avoid penalizing hospitals that transplanted higher-risk patients — the odds of dying within one year remained significantly greater at low-volume hospitals, the Plain Dealer's analysis showed.

The analysis showed that patients would have a better chance of survival at high-volume centers for all six major types of organ transplants — hearts, heart-lungs, livers, kidneys, lungs and pancreases.

"Everyone ought to be aware that volume is an important issue," said Dr. Lawrence G. Hunsicker, co-author with Hosenpud of the 1994 JAMA study and a heart transplant cardiologist at

the University of Iowa Hospital in Iowa City. Hunsicker is vice president of the United Network for Organ Sharing, the private, non-profit organization that holds the government contract to match donated organs with patients waiting for transplants.

"Clearly, what I take away from this is that the [heart] centers that regularly do fewer than 10 transplants a year should examine whether they should be in the business at all," Hunsicker said. "And what's hard to justify is places where there's two or three centers in a city, all of whom are doing seven transplants."

"That doesn't make any sense. They ought to get their acts together and get a single center that's got the volume to get the level of expertise that's needed."

In fact, four-fifths of the nation's low-volume heart transplant centers are in metropolitan areas that have another heart transplant center. Since 1988, the number of heart transplant programs has increased from 129 to 166.

"In principal, we would do better with fewer centers," Hunsicker added. "But you can't use volume as the only consideration."

Among the other considerations are ensuring that patients in rural, sparsely populated states have access to a transplant center.

The Health Care Financing Administration, an arm of the U.S. Department of Health and Human Services, has set minimum volume guidelines for hospitals to receive Medicare reimbursement for transplants. Heart and liver centers must perform at least 12 transplants a year, kidney centers must perform at least 15, while lung and heart-lung centers must do at least 10.

But many low-volume centers have chosen to continue their programs even though they don't do enough transplants to get federal reimbursement. And neither HHS' Division of Organ Transplantation nor UNOS has set volume or minimum-survival standards that cover non-Medicare patients.

"We don't have any way to actually remove a center from receiving organs, technically speaking," said Dr. James F. Burdick, president of UNOS and a transplant surgeon at Johns Hopkins Hospital. "That [volume] is not a question we've addressed directly because our job is to make things fair and work on centers that don't do well."

An exception

Although the Plain Dealer analysis showed that low-volume centers as a group had a higher one-year death rate, there are exceptions. One of them is the Via

Christie Regional Medical Center in Wichita, Kan.

The hospital performed an average of about eight heart transplants a year during the four years analyzed. Its one-year survival rate during that period was 100 percent, making it one of the three best-performing centers in the nation.

As of December, over the nine-year lifetime of its program, Via Christie had performed 102 heart transplants and 93 percent of those patients had survived on year. The national average is 81 percent.

"I think center volume does matter to an extent, but I think there are a lot of other things that add to the equation," said Dr. Thomas H. Estep, director of the heart transplant program.

Via Christie has the only heart transplant program in Kansas. The nearest center to it is a three-hour drive, in Kansas City, Mo.

Estep said attempts to limit the number of centers performing transplants should be based first on death rates, then on volume.

"If any center has poor outcomes, then I think that donor organs should go to other centers, where the chance of a patient living is greater," he said.

Because donor organs are scarce — for most types of transplants, there are about two people waiting for every one person who receives a transplant — transplant surgeons have hotly debated the best use of donor organs and whether to close low-volume centers. But that debate has remained within the fraternity. Few patients are aware that volume is a predictor of mortality, many doctors acknowledge.

"For the 5 percent who know all the statistics and know where I went to school, there's a whole host of people who are going wherever they're told to go," said Dr. Robert W. Stewart, head of the Cleveland Clinic's heart transplant program, one of the busiest in the country.

That wasn't the case with Anita Lupo, an administrator at Illinois State University who lives in Normal, Ill. Lupo, who is still working, has been on the waiting list for a heart transplant at Barnes Hospital in St. Louis since May 1995. Barnes is a high-volume center, averaging about 24 transplants a year.

Because she has twice undergone open-heart surgery, Lupo is considered to be at a higher risk for death or complications resulting from a transplant. That was a major factor in her evaluation of transplant centers, and she bypassed three programs closer to home — one in Peoria, Ill., and two in Chicago — because she thought they had not done enough transplants or because their surgical teams were too new.

She now has a much longer drive, about three hours, to go for her quarterly tests, but that doesn't bother her.

Lupo said she learned about the importance of volume when she sought a second opinion from a transplant cardiologist who was not involved in her care.

"He said don't go anywhere where they do less than 20 — that your quality is a lot better if you do at least 20 a year," Lupo said. "I am a believer that small-town hospitals and small-town doctors are not the place to go. So when I heard the number 20, that just reinforced what I already knew — that there had to be some minimum number, and that it just wouldn't be a good idea to go somewhere where they did less than that."

At that time, only 47 of the nation's 145 heart transplant centers, 32 percent, met that qualification.

Programs on probation

In many areas of medicine, the average number of procedures performed by doctors, nurses and technicians has long been considered a significant indicator of quality.

"As a physician, I strongly believe that the outcome does depend upon how many times you have performed a given procedure," said Dr. Peter Somani, Ohio's top health official. "Therefore, volume is important."

In addition to being the state director of health, Somani is on the board of the Ohio Solid Organ Transplant Consortium, the association that, with his department, oversees transplantation in Ohio. Somani's staff included volume requirements for all types of major organ transplants in the state's recently passed quality-assurance rules, which are designed to provide minimum standards for a wide variety of health care activities. The rules don't take effect until next fall.

"What we're saying is if your volume is less than the minimum, we'll automatically look at your results in more detail," Somani said.

The Ohio consortium has had volume requirements for several years, but it has no authority to close programs that don't meet them. And when hospitals are placed on probation for failing to perform enough transplants or for any other reason, that information is not made public because the consortium, a private organization, chooses not to disclose it.

In the past, minutes of the consortium's non-public board meetings have shown which transplant centers were placed on probation and why. But Audrey Bohnengel, the consortium's executive director, said the group would discontinue that practice after The Plain Dealer obtained consortium minutes through Somani's office showing that heart transplant programs at the Medical College of Ohio in Toledo and Ohio State University were placed on probation in 1996 for failing to perform

enough transplants.

The consortium requires heart transplant programs to perform a minimum of 12 transplants a year — the same number required by the federal government to obtain Medicare reimbursement.

According to consortium board minutes, Dr. Thomas E. Walsh, a board member and director of the heart transplant program at the Medical College of Ohio, argued against a volume requirement, saying, "There is no substantiation in literature that links volume to quality."

Walsh also said there were "better quality indicators than volume to demonstrate a successful program, such as length of stay, hospital charges and readmissions."

Last April, the consortium extended the Medical College's one-year probation for a second year for failure to meet volume standards. The hospital performed 15 heart transplants in 1996, and Walsh said in an interview that he expected the program to be taken off probation in April.

"My contention was that, despite the numbers, we've always had more than acceptable outcomes — that's mortality, readmissions, rejection, length of

stay and cost," Walsh said. "It seems to me that because we have a very small program where everything is done by a small, intimate group, that we profit by our experience much more greatly than if it was diffused over a large number of people."

OSU's heart transplant program has struggled even more to meet the volume standard. The center performed 11 transplants in 1995 and just seven in 1996.

Dr. P. David Myerowitz, director of OSU's heart transplant program, partly attributed the slowdown to the loss of two transplant cardiologists in 1996. That resulted in fewer patients — particularly fewer critically ill patients — being placed on OSU's waiting list.

Myerowitz also said that OSU, because it has a conservative approach about which hearts to accept for transplantation, occasionally turns away donor hearts that other programs use.

"It's the same way as how you invest your money," he said. "Some guys are on the fringe and some guys invest in CDs. That's an attitude of life. I admit I'm a conservative individual, and our program's probably conservative."

TRANSPLANTING LIFE

THE TRIUMPHS, THE TRAPS, THE TRAGEDIES

If you have a comment or a question about this series of articles, you can reach the reporters at the following phone numbers: Dave Davis — 999-4808, Joan Mazzolini — 999-4563 and Ted Wendling — 999-4987.

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Statistical analysis used most recent transplant data available

By DAVE DAVIS
PLAIN DEALER REPORTER

Records of 55,990 organ transplants performed over four years were analyzed for this story to determine whether low-volume transplant centers had a higher one-year mortality rate than high-volume centers.

The analysis included all heart, heart-lung, liver, lung, kidney and pancreas transplants in the United States between Oct. 1, 1987, and Dec. 31, 1991 — the most recent period for which records were available. Transplant patients were followed through 1993.

Based on the average number of transplants performed in a year, centers were labeled either high- or low-volume.

For each type of organ, roughly half of the centers in the country fell into each category. Low-volume centers, however, performed just 16 percent of the total organ transplants included in the



Bare



Meyer

analysis.

The analysis showed that, on average, patients who underwent a transplant at a low-volume center had a significantly greater chance of dying in the first year following the transplant. This was true for all six types of organ transplants.

The records also were analyzed to examine whether the increased rate of death was explained by differences in patients and donors, or whether a significant

portion of the increased rate could be attributed to transplant center volume.

Even when a sophisticated statistical method was used to adjust for differences in patient risk factors and donor characteristics — to avoid penalizing hospitals that undertook more difficult cases — the odds of dying remained greater at low-volume centers. Using that method, known as logistic regression, The Plain Dealer found that center volume was a significant predictor of mortality at one year.

The newspaper included the overall experience of a center, as expressed by the number of years it had operated, in risk-adjusting the data.

The Plain Dealer obtained transplant records on patients and donors — one record for each transplant — from the United Network for Organ Sharing, which holds a federal contract to match donor organs with waiting

patients. The information did not reveal the names of donors or recipients and is publicly available by calling UNOS at 1-800-243-6667.

The analysis was completed in SPSS for Windows version 6.1. The methodology for the analysis was developed with guidance from John Bare and Phillip Meyer.

Bare holds a doctorate in mass communication research from the University of North Carolina and is a research consultant in Chapel Hill, N.C. He helped develop the statistical methods used in numerous stories published by U.S. News & World Report and other news organizations.

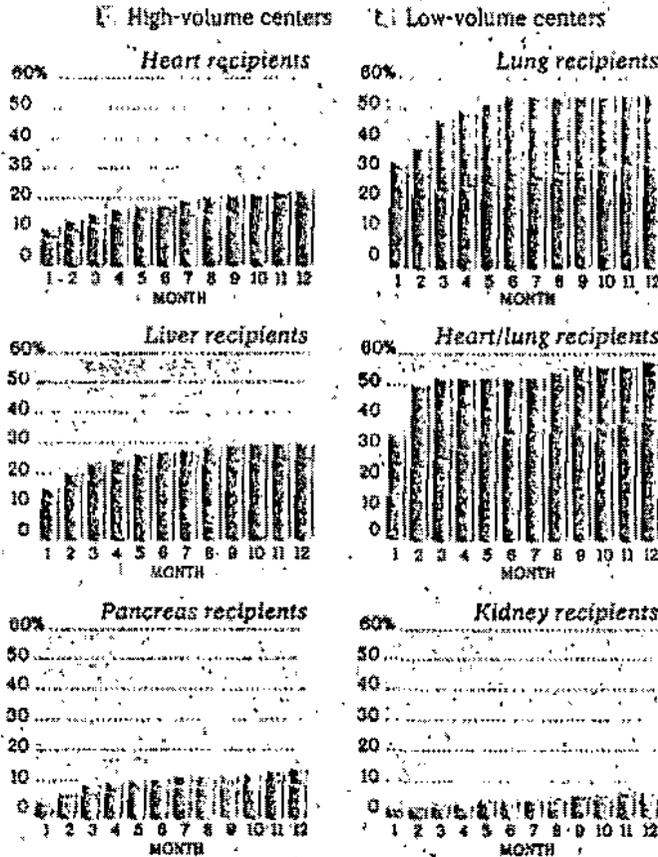
Meyer is the Knight Professor of Journalism at the University of North Carolina and the author of five books, including "The New Precision Journalism." He is a pioneer in the use of computers and social science research methods in journalism.

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SURVIVING A TRANSPLANT

DEATH RATES BY TYPE OF ORGAN

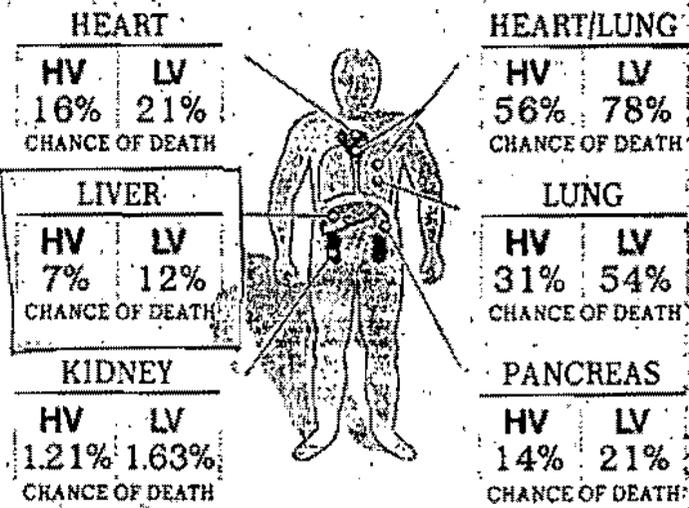
For each type of organ transplant, the death rate during the first year was always higher for low-volume centers.



INCREASED CHANCE OF DEATH WITHIN YEAR OF TRANSPLANT

All other factors being equal, patients face an increased risk of death within one year if they have an organ transplant at a low-volume center. For example, based on an analysis of the 55,990 organ transplants performed from Oct. 1, 1987, through 1991, the risk of death for a 40-year-old white male would increase at a low-volume center for each type of transplant. Patients with different characteristics would have different outcomes, but statistically would be expected to fare better at a high-volume center.

HV High-volume centers LV Low-volume centers



DEFINING HIGH- AND LOW-VOLUME CENTERS

High- and low-volume centers were defined in this analysis by the average number of transplants they performed in a year. For each organ type, roughly half the centers in the country fell into each group.

	HEART	HEART/LUNG	KIDNEY	LIVER	LUNG	PANCREAS
High-volume centers (9 or more)	9	2	27	14	3	6
Low-volume centers (8 or fewer)	8	1	26	13	2	5

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ORGAN TRANSPLANT CENTERS IN THE UNITED STATES - WAITING TIMES & MORTALITY RATES

This chart lists median waiting times, one-year mortality rates and volume for the nation's transplant centers, based on information compiled by the United Network for Organ Sharing. The median waiting time figure is in

days and is based on data from either 1994 or 1995. The mortality rate is for all transplants performed at a center over a four-year period beginning in October 1987. Volume shows the average annual number of transplants

at that center during those same four years. Although the figures listed below are the most recent available, patients may be able to obtain current information from individual centers.

WAIT- Median waiting time (days) **M**- One-year mortality rate **V**- Volume (average annual transplants)

HEART

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STATE	HOSPITAL	CITY	WAIT	M	Y
AL	U. of Alabama	Birmingham	180	12.8	27
AR	Baptist	Little Rock	284	23.1	4
AR	Arkansas	Little Rock	297	40.0	3
AR	University	Little Rock	84	NA	NA
AZ	University	Tucson	178	6.5	35
CA	Children's	Los Angeles	245	NA	NA
CA	Cedars-Sinai	Los Angeles	58	14.9	17
CA	U. Of Calif. - Irvine	Orange	NA	12.5	4
CA	Loma Linda U.	Loma Linda	52	15.7	45
CA	California Pacific	San Francisco	348	9.5	28
CA	Hoag Memrl	Newport Beach	NA	24.0	8
CA	UCSD	San Diego	57	5.0	10
CA	U. Of California	San Francisco	201	15.4	13
CA	Sutter Memrl	Sacramento	368	4.8	7
CA	Donald N. Sharp Memrl	San Diego	408	8.2	18
CA	U. of Calif. Davis	Sacramento	NA	0.0	1
CA	Stanford U.	Palo Alto	98	18.1	47
CA	St. Vincent	Los Angeles	86	4.5	6
CA	UCLA	Los Angeles	157	15.0	56
CA	USC	Los Angeles	184	NA	NA
CO	Children's	Denver	69	12.5	4
CO	Presby/St. Luke's	Denver	NA	33.9	8
CO	University	Denver	87	10.7	9
CT	Hartford	Hartford	188	13.0	14
CT	Yale New Haven	New Haven	NA	28.3	12
DC	Children's NMC	Washington	NA	57.1	2
DC	Georgetown U.	Washington	NA	6.3	4
DC	George Washington U.	Washington	NA	10.0	3
DC	Washington	Washington	212	8.3	12
FL	Jackson Memrl	Miami	51	17.5	10
FL	Tampa General	Tampa	177	18.1	28
FL	Tallahassee Memrl	Tallahassee	79	23.5	9
FL	Shands Teaching	Gainesville	87	12.8	22
GA	Henrietta Egston	Atlanta	27	17.8	4
GA	Emory U.	Atlanta	665	7.2	21
GA	St. Joseph's	Atlanta	280	15.8	30
HI	St. Francis	Honolulu	NA	20.0	3
IA	U. Of Iowa	Iowa City	389	29.3	10
IA	Mercy Hospital	Des Moines	48	21.4	7
IL	Children's Memrl	Chicago	183	27.3	8
IL	Evanston	Evanston	NA	13.6	6
IL	Loyola U.	Maywood	430	21.8	30
IL	Rush-Presby-St. Luke's	Chicago	249	38.4	3
IL	St. Francis	Peoria	407	18.2	11
IL	U. Of Chicago	Chicago	332	33.3	2
IL	U. Of Illinois	Chicago	NA	20.0	4
IL	Hines VA	Hines	NA	38.5	7
IN	Methodist	Indianapolis	189	20.8	18
IN	Indiana U.	Indianapolis	181	12.2	19
IN	Lutheran	Fort Wayne	544	22.2	18
IN	St. Vincent	Indianapolis	378	29.0	8
KS	St. Francis	Wichita	NA	0.0	8
KS	U. Of Kansas	Kansas City	NA	5.7	9
KY	Audubon Regional	Louisville	NA	50.0	2
KY	Jewish	Louisville	294	21.7	15
KY	Kosair Children's	Louisville	NA	68.7	4
KY	University	Lexington	273	29.4	17
LA	Ochsner	New Orleans	107	12.1	27
LA	Tulane	New Orleans	80	NA	NA
LA	Willis Knighton	Shreveport	768	10.7	34
MA	Children's	Boston	93	6.3	4
MA	Massachusetts General	Boston	93	18.2	9
MA	New England	Boston	93	21.1	5
MA	Brighton & Women's	Boston	93	17.4	33
MD	Johns Hopkins	Baltimore	223	23.9	17
MD	U. Of Maryland	Baltimore	138	42.9	2
MI	William Beaumont	Royal Oak	297	40.0	2
MI	Henry Ford	Detroit	206	8.7	15
MI	Harper Grace	Detroit	NA	44.4	8
MI	U. of Michigan	Ann Arbor	328	18.7	34
MN	Abbott Northwestern	Minneapolis	NA	14.7	24
MN	St. Mary's	Rochester	594	17.4	7
MN	U. Of Minnesota	Minneapolis	815	12.6	24
MO	Barnes	St. Louis	139	8.7	26
MO	Cardinal Glennon Memrl	St. Louis	NA	44.4	2
MO	St. Louis Children's	St. Louis	38	18.7	8
MO	St. Luke's	Kansas City	248	15.8	14
MO	Memorial	Kansas City	NA	83.3	2
MO	St. Louis U.	St. Louis	371	10.9	22
MO	University	Columbia	188	13.3	5
MS	U. Of Mississippi	Jackson	101	11.1	5
NC	North Carolina Baptist	Winst-Salem	298	75.0	2
NC	Carolinas	Charlotte	202	19.0	20
NC	Duke U.	Durham	124	14.0	13
NC	Pitt County Memrl	Greenville	NA	60.0	1
NC	U. Of North Carolina	Chapel Hill	359	21.2	8
NE	Bryan Memrl	Lincoln	NA	9.7	8
NE	St. Joseph	Omaha	NA	50.0	2
NE	U. Of Nebraska	Omaha	100	NA	NA
NJ	Newark Beth Israel	Newark	83	25.0	14
NM	Presby.	Albuquerque	139	18.8	15
NY	Children's	Buffalo	NA	0.0	1
NY	Buffalo General	Buffalo	NA	35.3	9
NY	Presby.	New York	149	23.5	85
NY	Mount Sinai	New York	NA	15.6	11
NY	VA	Buffalo	NA	37.5	2

OH	Cleveland Clinic	Cleveland	149	14.3	28
OH	Children's	Cincinnati	NA	14.3	4
OH	Medical College Of Ohio	Toledo	NA	16.7	6
OH	Ohio State	Columbus	NA	20.0	15
OR	U. Of Cincinnati	Cincinnati	122	13.0	17
OK	Baptist	Oklahoma City	428	9.6	28
OK	Children's	Oklahoma City	NA	66.7	3
OK	University	Oklahoma City	211	30.8	3
OK	St. Anthony	Oklahoma City	NA	100.0	NA
OK	St. Francis	Tulsa	374	NA	NA
OR	Oregon Health Sciences	Portland	116	13.8	31
PA	Allegheny General	Pittsburgh	740	14.0	13
PA	Children's	Pittsburgh	153	27.5	10
PA	Children's	Philadelphia	71	37.5	8
PA	Penn St/Hershey	Hershey	250	18.9	13
PA	Hahnemann U.	Philadelphia	94	0.0	4
PA	Presby-U.	Pittsburgh	436	12.2	44
PA	St. Christopher For Childr	Philadelphia	59	57.1	4
PA	Temple U.	Philadelphia	78	21.4	35
PA	U. Of Penna.	Philadelphia	147	23.4	16
SC	Medical U.	Charleston	374	10.9	12
TN	Baptist Memrl	Memphis	215	15.8	8
TN	LeBonheur Children's	Memphis	NA	16.7	2
TN	Methodist	Memphis	NA	13.9	9
TN	St. Thomas	Nashville	333	18.2	11
TN	Vanderbilt	Nashville	153	11.5	26
TX	UTHSC at San Antonio	San Antonio	NA	18.4	13
TX	Children's	Dallas	NA	18.7	3
TX	Seton	Austin	80	20.4	14
TX	Medical City Dallas	Dallas	28	40.0	5
TX	St. Luke's Episcopal	Houston	175	20.7	56
TX	San Antonio Regional	San Antonio	147	19.8	13
TX	U. Of Texas	Galveston	222	NA	NA
TX	Methodist	Lubbock	82	0.0	4
TX	Methodist	Dallas	271	13.5	9
TX	Methodist	Houston	53	29.9	36
TX	St. Paul	Dallas	173	8.4	21
TX	Baylor	Dallas	351	28.4	24
UT	Latter-Day Saints	Salt Lake City	253	7.7	23
UT	U. Of Utah	Salt Lake City	135	19.3	29
UT	Primary Children's	Salt Lake City	151	0.0	1
UT	VA	Salt Lake City	143	22.2	20
VA	Children's Kings Daughter	Falls Church	NA	30.0	5
VA	Fairfax	Falls Church	285	7.0	11
VA	Henrietta Doctors	Richmond	348	23.8	7
VA	Medical College Of Va.	Richmond	292	19.8	29
VA	McGuire VA	Richmond	NA	14.5	16
VA	Sentara Norfolk General	Norfolk	307	17.0	10
VA	U. of Va.	Charlottesville	355	20.0	15
WA	Sacred Heart	Spokane	289	6.7	15
WA	University	Seattle	104	11.4	20
WI	Children's Of Wisconsin	Milwaukee	NA	100.0	1
WI	John L. Doyle	Milwaukee	NA	31.4	8
WI	St. Luke's	Milwaukee	241	17.6	26
WI	U. Of Wisconsin	Madison	117	19.6	14

LIVER

STATE	HOSPITAL	CITY	WAIT	#	V
AL	U. of Alabama	Birmingham	88	12.5	14
AZ	Good Samaritan	Phoenix	130	41.5	10
AZ	University	Tucson	242	NA	NA
CA	Cedars-Sinai	Los Angeles	120	15.9	29
CA	The Green	La Jolla	333	29.5	11
CA	U. Of Calif-Irvine	Orange	86	NA	NA
CA	Loma Linda U.	Loma Linda	154	NA	NA
CA	California Pacific	San Francisco	473	12.5	65
CA	UCSD	San Diego	236	100.0	0
CA	U. Of California	San Francisco	NA	13.6	74
CA	U. of Calif. Davis	Sacramento	299	NA	NA
CA	Stanford U.	Palo Alto	NA	0.0	2
CA	St. Vincent	Los Angeles	327	NA	NA
CA	UCLA	Los Angeles	NA	23.2	140
CO	Children's	Denver	278	20.0	5
CO	University	Denver	405	12.1	24
CT	Hartford	Hartford	147	33.3	7
CT	Yale New Haven	New Haven	NA	60.9	6
DC	Howard U.	Washington	138	100.0	1
FL	Jackson Memrl	Miami	64	45.0	15
FL	Tampa General	Tampa	NA	75.0	1
FL	Shands Teaching	Gainesville	97	23.1	13
GA	Henrietta Egleson	Atlanta	77	22.2	5
GA	Emory U.	Atlanta	159	22.7	24
IA	U. Of Iowa	Iowa City	140	18.5	7
IL	Rush-Presby. St. Luke's	Chicago	423	39.0	34
IL	U. Of Chicago	Chicago	306	35.5	70
IL	U. Of Illinois	Chicago	NA	57.9	57
IN	Methodist	Indianapolis	385	28.7	11
IN	Indiana U.	Indianapolis	382	28.8	26
KS	U. Of Kansas	Kansas City	21	22.6	16
KY	Jewish	Louisville	38	35.3	9
KY	University	Lexington	226	NA	NA
LA	University	New Orleans	262	NA	NA
LA	Ochsner	New Orleans	209	29.5	29
LA	Louisiana State U.	Shreveport	NA	33.3	10
LA	Tulane	New Orleans	18	NA	NA
LA	Willis Knighton	Shreveport	189	22.2	9
MA	Children's	Boston	648	23.4	8
MA	New England Deaconess	Boston	648	28.3	41
MA	Massachusetts General	Boston	648	26.8	21
MA	New England	Boston	648	24.0	25
MA	Brigham & Women's	Boston	648	NA	NA
MD	Johns Hopkins	Baltimore	563	30.5	30
MD	U. Of Maryland	Baltimore	518	NA	NA
MI	Henry Ford	Detroit	161	28.7	5
MI	U. of Michigan	Ann Arbor	401	23.7	69
MN	Rochester Methodist	Rochester	182	13.3	50
MN	St. Mary's	Rochester	124	NA	NA
MN	U. Of Minnesota	Minneapolis	258	NA	NA
MO	Barnes	St. Louis	240	29.0	30
MO	Cardinal Gleannon Memrl	St. Louis	NA	20.0	2
MO	St. Louis Children's	St. Louis	222	29.4	8
MO	St. Louis U.	St. Louis	215	33.8	9
MS	U. Of Mississippi	Jackson	NA	33.3	1
NC	Carolina's	Charlotte	190	NA	NA
NC	Duke U.	Durham	210	39.0	22
NC	U. Of North Carolina	Chapel Hill	206	25.0	4
NE	U. Of Nebraska	Omaha	267	20.4	119
NJ	University	Newark	40	30.8	13
NM	U. Of New Mexico	Albuquerque	151	NA	NA
NY	Strong Memrl	Rochester	174	NA	NA
NY	Mount Sinai	New York	215	19.2	67
NY	NYU	New York	NA	10.5	10
OH	Cleveland Clinic	Cleveland	394	24.1	22
OH	Children's	Columbus	NA	16.7	2
OH	Children's	Cincinnati	132	19.6	14
OH	Ohio State	Columbus	104	20.8	18
OH	U. Of Cincinnati	Cincinnati	258	18.5	7
OH	University	Cleveland	445	13.5	9
OK	Baptist	Okla. City	83	NA	NA
OK	University	Okla. City	NA	100.0	1
OR	Oregon Health Sciences	Portland	123	19.4	9
OR	VA	Portland	170	25.0	7
PA	Albert Einstein	Philadelphia	224	0.0	1
PA	Children's	Pittsburgh	323	20.8	72
PA	Children's	Philadelphia	124	37.5	11
PA	Presby. U.	Pittsburgh	272	21.5	357
PA	St. Christopher For Childm.	Philadelphia	368	12.5	12
PA	Thomas Jefferson U.	Philadelphia	348	31.9	18
PA	U. Of Penna.	Philadelphia	274	36.6	24
PA	VA	Pittsburgh	152	15.6	16
SC	Medical U.	Charleston	99	13.3	8
TN	Lebonheur Children's	Memphis	NA	11.1	2
TN	U. Of Tennessee	Memphis	96	29.0	13
TN	Vanderbilt	Nashville	71	20.0	10
TX	UTHSC at San Antonio	San Antonio	229	NA	NA
TX	Children's	Dallas	42	27.6	23
TX	Hermann	Houston	223	42.3	7
TX	St. Luke's Episcopal	Houston	175	NA	NA
TX	Methodist	Houston	NA	51.4	9
TX	Texas Children's	Houston	149	26.9	3
TX	Baylor U.	Dallas	233	18.7	109
TX	Wilford Hall	Lackland AFB	184	50.0	7
UT	Latter-Day Saints	Salt Lake City	82	30.0	15
VA	Fairfax	Falls Church	320	NA	NA
VA	Medical College Of Va.	Richmond	253	32.5	20
VA	U. of Va.	Charlottesville	100	21.5	27
WA	Children's	Seattle	NA	0.0	3
WA	University	Seattle	271	16.9	36
WI	Children's Of Wisconsin	Milwaukee	NA	0.0	4
WI	Froedtert Memrl. Luthn.	Milwaukee	NA	28.8	14
WI	U. Of Wisconsin	Madison	54	15.4	57

KIDNEY

STATE	HOSPITAL	CITY	WAST	H	V
AL	U. of Alabama	Birmingham	NA	5.9	255
AR	Baptist	Little Rock	581	8.3	16
AR	Arkansas	Little Rock	NA	9.4	8
AR	University	Little Rock	251	5.3	35
AZ	Good Samaritan	Phoenix	630	8.1	88
AZ	Healthwest Regional	Phoenix	NA	25.0	1
AZ	St. Joseph's	Phoenix	390	3.8	20
AZ	VA	Tucson	NA	11.0	23
AZ	University	Tucson	705	0.0	1
CA	St. Bernardine	San Bernardino	NA	5.7	27
CA	Alta Bates	Berkeley	NA	5.0	41
CA	Children's	Los Angeles	NA	2.7	19
CA	Cedars-Sinai	Los Angeles	733	4.8	42
CA	U. Of Calif-Irvine	Orange	NA	5.8	28
CA	LA County Harbor-UCLA	Torrance	NA	7.7	40
CA	St. Mary	Long Beach	NA	3.4	15
CA	Loma Linda U.	Loma Linda	NA	4.8	44
CA	Santa Rosa Memrl.	Santa Rosa	NA	6.7	22
CA	California Pacific	San Francisco	NA	8.1	171
CA	San Bernardino County	San Bernard	NA	9.9	18
CA	USC -LA. County	Los Angeles	NA	10.8	30
CA	UCSD	San Diego	NA	5.2	89
CA	U. Of California	San Francisco	NA	7.0	232
CA	Sutter Memrl.	Sacramento	NA	12.5	26
CA	Donald N. Sharp Memrl.	San Diego	NA	2.0	15
CA	St. Joseph	Orange	NA	4.0	31
CA	U. of Calif. Davis	Sacramento	581	8.0	28
CA	Stanford U.	Palo Alto	NA	0.0	5
CA	St. Vincent	Los Angeles	NA	7.4	208
CA	UCLA	Los Angeles	NA	2.4	108
CA	USC	Los Angeles	NA	0.0	2
CA	Western	Santa Ana	NA	2.7	19
CO	Children's	Denver	NA	0.0	1
CO	Porter Memrl.	Denver	NA	8.9	23
CO	Presby/St. Luke's	Denver	872	6.0	70
CO	University	Denver	585	2.2	35
CT	Hartford	Hartford	481	8.7	64
CT	Yale New Haven	New Haven	NA	5.8	39
DC	Children's NMC	Washington	NA	11.8	9
DC	Georgetown U.	Washington	NA	5.8	37
DC	George Washington U.	Washington	NA	5.3	10
DC	Howard U.	Washington	381	23.1	15
DC	Washington	Washington	NA	5.0	123
DC	Walter Reed Army	Washington	NA	6.8	22
FL	All Children's	St. Petersburg	NA	9.1	4
FL	Florida	Orlando	289	7.1	78
FL	Southwest Florida	Fort Meyers	114	4.2	6
FL	Jackson Memrl.	Miami	166	4.7	94
FL	Methodist	Jacksonville	396	8.5	11
FL	Tampa General	Tampa	314	7.1	128
FL	Shands Teaching	Gainesville	451	6.2	133
GA	Henrietta Egleston	Atlanta	144	4.0	13

GA	Emory U.	Atlanta	412	3.5	117
GA	Medical College Of Georgia	Augusta	NA	4.1	67
GA	Piedmont	Atlanta	340	5.9	66
HI	St. Francis	Honolulu	NA	6.5	27
IA	Iowa Methodist	Des Moines	438	2.1	12
IA	U. Of Iowa	Iowa City	333	5.0	75
IA	Mercy Hospital	Des Moines	NA	10.2	10
IL	Children's Memrl.	Chicago	NA	2.0	13
IL	Loyola U.	Maywood	NA	4.2	42
IL	Memrl.	Springfield	332	8.2	12
IL	Northwestern Memrl.	Chicago	828	8.2	37
IL	Rush-Presby-St. Luke's	Chicago	370	8.7	76
IL	St. Francis	Peoria	331	9.1	22
IL	U. Of Chicago	Chicago	NA	6.2	82
IL	U. Of Illinois	Chicago	NA	5.7	54
IL	Hines VA	Hines	NA	0.0	1
IN	Methodist	Indianapolis	419	2.4	52
IN	Indiana U.	Indianapolis	476	3.7	102
KS	St. Francis	Wichita	273	5.7	39
KS	U. Of Kansas	Kansas City	457	6.6	30
KY	Jewish	Louisville	NA	7.7	62
KY	Kosair Children's	Louisville	NA	6.3	4
KY	University	Lexington	215	8.0	57
LA	University	New Orleans	710	12.4	22
LA	Ochsner	New Orleans	388	3.9	40
LA	S. Baptist	New Orleans	NA	5.3	5
LA	Schumpert	Shreveport	391	3.2	18
LA	Louisiana State U.	Shreveport	NA	6.4	24
LA	Tulane	New Orleans	208	4.9	36
LA	Wills Knighton	Shreveport	584	7.5	21
MA	Beth Israel	Boston	NA	6.8	28
MA	Baystate	Springfield	490	6.5	27
MA	Boston U.	Boston	NA	8.2	27
MA	VA	Boston	NA	0.0	14
MA	Children's	Boston	NA	8.8	19
MA	New England Deaconess	Boston	NA	8.0	57
MA	Lahey	Burlington	NA	6.7	8
MA	Massachusetts General	Boston	NA	5.0	70
MA	New England	Boston	NA	4.5	29
MA	Brigham & Women's	Boston	NA	5.3	61
MA	U. of Massachusetts	Worcester	490	3.0	28
MD	Francis Scott Key	Baltimore	761	6.4	25
MD	Johns Hopkins	Baltimore	NA	8.5	54
MD	U. Of Maryland	Baltimore	NA	5.8	26
ME	Maine	Portland	NA	6.1	41
MI	William Beaumont	Royal Oak	850	3.5	36
MI	Children's	Detroit	319	5.9	NA
MI	Henry Ford	Detroit	NA	7.3	72
MI	Harper Grace	Detroit	NA	14.8	20
MI	Hudley	Flint	NA	6.0	15
MI	Borgess	Kalamazoo	NA	14.9	20
MI	St. John	Detroit	NA	8.7	12
MI	St. Mary's	Grand Rapids	NA	4.8	47
MI	U. of Michigan	Ann Arbor	NA	5.7	99
MN	Hennepin County	Minneapolis	NA	6.5	64
MN	Rochester Methodist	Rochester	628	3.6	70
MN	Metropolitan	Minneapolis	NA	5.9	9

MO	Barnes	St. Louis	387	4.4	79
MO	Cardinal Glennon Memrl	St. Louis	NA	0.0	3
MO	St. Louis Children's	St. Louis	NA	4.1	12
MO	Children's Mercy	Kansas City	NA	0.0	1
MO	DePaul	Bridgeton	NA	0.0	7
MO	St. Luke's	Kansas City	245	8.6	41
MO	Research	Kansas City	733	4.9	26
MO	St. Louis U.	St. Louis	NA	7.4	42
MO	University	Columbia	271	8.3	34
MS	U. Of Mississippi	Jackson	NA	3.6	21
NC	North Carolina Baptist	Winst-Salem	NA	8.2	37
NC	Carolinas	Charlotte	302	10.0	51
NC	Duke U.	Durham	NA	4.4	63
NC	VA	Durham	NA	8.1	8
NC	Pitt County Memrl	Greenville	NA	10.9	26
NC	U. Of North Carolina	Chapel Hill	810	4.8	39
ND	Dakota	Fargo	NA	7.7	9
ND	Medcenter One	Bismarck	NA	0.0	7
ND	St. Luke's	Fargo	NA	13.3	4
NE	Bishop Clarkson Memrl	Omaha	338	3.5	57
NE	AMI St. Joseph	Omaha	381	4.9	11
NE	U. Of Nebraska	Omaha	408	0.0	1
NJ	Newark Beth Israel	Newark	NA	8.2	42
NJ	Our Lady Of Lourdes	Camden	450	6.3	21
NJ	St. Barnabas	Livingston	NA	9.4	49
NM	U. Of New Mexico	Albuquerque	461	4.5	39
NM	Presby.	Albuquerque	468	12.1	23
NV	Sunrise	Las Vegas	475	9.4	8
NV	U.M.C. Of S. Nevada	Las Vegas	417	3.7	7
NY	Albany	Albany	538	4.2	60
NY	Children's	Buffalo	NA	5.6	5
NY	Buffalo General	Buffalo	NA	9.0	25
NY	Presby.	New York	NA	5.7	53
NY	Suny Downstate U.	Brooklyn	NA	5.2	77
NY	Erle County	Buffalo	654	12.2	12
NY	Syring Memrl	Hochester	249	6.8	45
NY	Montefiore	Bronx	NA	3.4	75
NY	Mount Sinai	New York	812	4.7	39
NY	New York	New York	NA	8.5	53
NY	University	Stony Brook	583	4.1	31
NY	St. Luke's-Roosevelt	New York	NA	5.8	17
NY	NYU	New York	NA	10.0	5
NY	Suny at Syracuse	Syracuse	414	10.3	32
NY	Westchester County	Valhalla	727	4.6	35
OH	Akron City	Akron	NA	4.6	27
OH	Children's	Akron	NA	0.0	3
OH	Cleveland Clinic	Cleveland	NA	5.7	80
OH	Children's	Cincinnati	NA	8.1	10
OH	Medical College Of Ohio	Toledo	216	6.5	42
OH	Miami Valley	Dayton	204	5.7	22
OH	Ohio State U.	Columbus	431	8.8	180
OH	St. Elizabeth	Youngstown	NA	5.1	15
OH	Chrst	Cincinnati	260	4.5	39
OH	U. Of Cincinnati	Cincinnati	174	6.1	40
OH	University	Cleveland	NA	5.1	52
OK	Baptist	Okla. City	230	10.5	27
OK	Children's	Okla. City	NA	7.8	13
OK	Hillcrest	Tulsa	490	9.9	23
OK	University	Okla. City	559	6.3	21
OK	St. Anthony	Okla. City	436	16.2	27
OR	Oregon Health Sciences	Portland	147	3.4	118
PA	Albert Einstein	Philadelphia	NA	8.4	57
PA	Allegheny General	Pittsburgh	520	8.8	67
PA	Children's	Pittsburgh	205	3.8	7
PA	Geisinger	Danville	486	13.5	38
PA	Penn St/Hershey	Hershey	858	5.4	65
PA	Hahnemann U.	Philadelphia	807	5.3	34
PA	Lehigh Valley	Allentown	838	0.0	1
PA	Presby. U.	Pittsburgh	79	7.0	195
PA	St. Christopher For Childrn	Philadelphia	NA	2.7	19
PA	Thomas Jefferson U.	Philadelphia	NA	2.4	75
PA	Temple U.	Philadelphia	438	0.0	7
PA	U. Of Penna	Philadelphia	822	3.7	119
PR	Audilo Munis	Hato Rey	NA	8.3	36
SC	Medical U.	Charleston	NA	4.3	88
TN	Erlanger	Chattanooga	434	4.5	17
TN	Johnson City	Johnson City	309	4.2	6
TN	Lebonheur Children's	Memphis	NA	10.0	5
TN	VA	Nashville	NA	7.8	12
TN	Centennial/Parkeview	Nashville	487	1.7	15
TN	St. Thomas	Nashville	NA	0.0	5
TN	U. Of Tennessee	Knoxville	NA	5.6	36
TN	U. Of Tennessee	Memphis	514	6.8	70
TN	Vanderbilt	Nashville	NA	2.9	86
TX	Brackerridge	Austin	437	3.3	31
TX	UTHSC at San Antonio	San Antonio	427	10.0	15
TX	Children's	Dallas	210	8.5	12
TX	Harris Methodist	Fort Worth	54	2.0	25
TX	Hermann	Houston	NA	7.5	103
TX	St. Luke's Episcopal	Houston	333	7.9	33
TX	San Antonio Regional	San Antonio	611	5.6	83
TX	U. Of Texas	Galveston	344	6.5	72
TX	University	Lubbock	154	5.1	10
TX	Methodist	Lubbock	163	0.0	7
TX	Methodist	Dallas	315	4.1	109
TX	Methodist	Houston	466	3.6	43
TX	Parkland Memrl	Dallas	763	5.2	56
TX	Sierra	El Paso	368	0.0	3
TX	Texas Children's	Houston	188	4.5	6
TX	Baylor U.	Dallas	376	7.1	46
TX	East Texas	Tyler	227	2.8	19
TX	Wilford Hall	Wackland AFB	345	7.2	46
UT	Latter-Day Saints	Salt Lake City	360	11.8	76
UT	U. Of Utah	Salt Lake City	328	4.7	48
VA	Henrico Doctors	Richmond	NA	4.2	6
VA	Medical College Of Va.	Richmond	NA	4.2	48
VA	Sentara Norfolk General	Norfolk	857	8.6	80
VA	U. of Va.	Charlottesville	388	4.3	47
VT	Medical Center Of Vermont	Burlington	NA	13.9	21
WA	Children's	Seattle	NA	4.0	6
WA	Sacred Heart	Spokane	193	7.9	27
WA	Swedish	Seattle	NA	7.3	56
WA	University	Seattle	NA	4.6	38
WA	Va. Mason	Seattle	759	7.3	97
WI	Children's Of Wisconsin	Milwaukee	NA	4.8	6
WI	Froedtert Memrl. Luthm.	Milwaukee	725	7.3	114
WI	U. Of Wisconsin	Madison	754	2.9	202
WV	Charleston Area	Charleston	NA	8.6	25
WV	West Va. U.	Morgantown	668	4.7	13

PANCREAS

STATE	HOSPITAL	CITY	WAIT	M	V
AL	U. of Alabama	Birmingham	NA	31.8	6
AR	University	Little Rock	NA	16.7	16
CA	California Pacific	San Francisco	NA	30.8	4
CA	U. Of California	San Francisco	NA	2.9	12
CA	U. of Calif. Davis	Sacramento	NA	12.5	3
CA	Stanford U.	Palo Alto	NA	0.0	1
CA	UCLA	Los Angeles	NA	0.0	1
CO	Presby/St. Luke's	Denver	NA	22.2	3
DC	Georgetown U.	Washington	NA	0.0	4
DC	Washington	Washington	NA	10.0	10
FL	Jackson Memrl.	Miami	NA	0.0	3
IA	U. Of Iowa	Iowa City	NA	12.9	18
IL	U. Of Chicago	Chicago	NA	7.9	16
IL	U. Of Illinois	Chicago	NA	33.3	6
IN	Indiana U.	Indianapolis	NA	14.3	5
KS	St. Francis	Wichita	NA	25.0	1
KY	Jewish	Louisville	NA	15.0	5
LA	Ochsner	New Orleans	NA	0.0	7
MD	U. Of Maryland	Baltimore	600	0.0	9
MA	Beth Israel	Boston	NA	20.0	3
MA	New England Deaconess	Boston	NA	3.6	7
MA	Massachusetts General	Boston	NA	8.7	8
MI	Henry Ford	Detroit	NA	11.1	2
MI	U. of Michigan	Ann Arbor	NA	50.0	1
MN	Rochester Methodist	Rochester	NA	8.3	9
MN	U. Of Minnesota	Minneapolis	181	11.2	49
MO	St. Louis U.	St. Louis	NA	5.8	9
NC	Duke U.	Durham	NA	5.8	12
NE	Bishop Clarkson Memrl.	Omaha	NA	4.2	24
NY	Montefiore	Bronx	NA	50.0	11
OH	Cleveland Clinic	Cleveland	NA	8.3	4
OH	Ohio State	Columbus	290	7.6	33
OH	U. Of Cincinnati	Cincinnati	NA	10.5	5
OH	University	Cleveland	NA	5.0	10
OR	Oregon Health Sciences	Portland	NA	8.7	5
PA	Albert Einstein	Philadelphia	NA	11.1	11
PA	Allegheny General	Pittsburgh	NA	40.0	3
PA	Penn St/Hershey	Hershey	NA	0.0	3
PA	U. Of Penna.	Philadelphia	NA	2.5	10
SC	Medical U.	Charleston	99	11.1	9
TN	Centennial/Parkview	Nashville	NA	0.0	3
TN	U. Of Tennessee	Memphis	NA	13.0	15
TN	Vanderbilt	Nashville	NA	17.8	6
TX	U. Of Texas	Galveston	NA	9.1	8
TX	Methodist	Dallas	NA	0.0	7
TX	Methodist	Houston	NA	15.4	7
TX	Parkland Memrl.	Dallas	NA	9.1	6
TX	Wilford Hall	Lackland AFB	NA	27.3	4
UT	Latter-Day Saints	Salt Lake City	NA	17.4	12
VA	U. of Va.	Charlottesville	NA	5.3	5
WA	University	Seattle	NA	3.8	14
WI	Froedtert Memrl. Luthrn.	Milwaukee	NA	7.9	10
WI	U. Of Wisconsin	Madison	NA	4.3	41

HEART - LUNG

STATE	HOSPITAL	CITY	WAIT	M	V
AL	U. of Alabama	Birmingham	NA	0.0	1
AZ	University	Tucson	NA	28.7	4
CA	UCSD	San Diego	NA	0.0	1
CA	Stanford U.	Palo Alto	595	33.3	14
CO	Presby/St. Luke's	Denver	NA	75.0	1
GA	Emory U.	Atlanta	NA	75.0	1
IA	U. Of Iowa	Iowa City	NA	100.0	1
IL	Loyola U.	Maywood	NA	60.0	2
IN	Methodist	Indianapolis	NA	50.0	1
LA	Ochsner	New Orleans	NA	0.0	1
MI	U. of Michigan	Ann Arbor	NA	100.0	1
MN	Abbott-Northwestern	Minneapolis	NA	18.7	2
MN	U. Of Minnesota	Minneapolis	NA	20.0	5
MO	St. Louis U.	St. Louis	NA	75.0	1
NC	U. Of North Carolina	Chapel Hill	NA	50.0	2
NY	Presby.	New York	NA	63.6	3
PA	Children's	Pittsburgh	NA	0.0	2
PA	Presby-U.	Pittsburgh	NA	43.5	6
TN	Baptist Memrl.	Memphis	NA	0.0	1
TN	Vanderbilt	Nashville	NA	33.3	3
TX	San Antonio Regional	San Antonio	147	75.0	1
TX	Baylor	Dallas	NA	100.0	2
VA	Medical College Of Va.	Richmond	NA	25.0	1
VA	McGuire VA	Richmond	NA	100.0	1
VA	U. of Va.	Charlottesville	528	30.0	5
WA	Sacred Heart	Spokane	NA	25.0	8
WA	University	Seattle	NA	248	NA
WI	John L. Doyne	Milwaukee	155	0.0	2
WI	U. Of Wisconsin	Madison	162	50.0	1

LUNG

STATE	HOSPITAL	CITY	WAIT	M	V
AL	U. of Alabama	Birmingham	77	33.3	3
AZ	University	Tucson	NA	37.5	4
CA	Cedars-Sinai	Los Angeles	273	43.3	8
CA	UCSD	San Diego	371	5.6	9
CA	U. Of California	San Francisco	269	0.0	1
CA	Donald N. Sharp Memrl.	San Diego	NA	33.3	2
CA	U. of Calif. Davis	Sacramento	130	NA	NA
CA	Stanford U.	Palo Alto	363	34.8	8
CA	UCLA	Los Angeles	417	33.3	2
CO	Presby/St. Luke's	Denver	NA	77.8	2
CO	University	Denver	333	NA	NA
FL	Shands Teaching	Gainesville	124	NA	NA
GA	Emory U.	Atlanta	239	NA	NA
IA	U. Of Iowa	Iowa City	NA	57.1	2
IL	Loyola U.	Maywood	274	40.0	4
IL	U. Of Illinois	Chicago	282	NA	NA
IN	Methodist	Indianapolis	598	0.0	7
IN	Indiana U.	Indianapolis	NA	25.0	4
IN	Lutheran	Fort Wayne	NA	60.0	2
KY	Jewish	Louisville	233	0.0	1
KY	University	Lexington	114	100.0	1
LA	Ochsner	New Orleans	43	50.0	2
MA	Children's	Boston	NA	50.0	1
MA	Mass. General	Boston	NA	28.6	7
MA	Brigham & Women's	Boston	NA	27.3	7
MI	U. of Michigan	Ann Arbor	793	30.0	10
MN	Abbott-Northwestern	Minneapolis	NA	22.2	2
MN	St. Mary's	Rochester	NA	33.3	3
MN	U. Of Minnesota	Minneapolis	368	19.4	8
MO	Barnes	St. Louis	690	23.6	27
MO	St. Louis Children's	St. Louis	408	53.8	7
MO	St. Louis U.	St. Louis	NA	28.6	2
MS	U. Of Mississippi	Jackson	NA	66.7	3
NC	Duke U.	Durham	449	NA	NA
NC	U. Of North Carolina	Chapel Hill	762	16.7	18
NJ	Newark Beth Israel	Newark	347	NA	NA
NY	Presbyterian	New York	801	36.1	12
OH	Cleveland Clinic	Cleveland	332	43.5	12
OK	Baptist	Olda City	NA	33.3	3
PA	Children's	Pittsburgh	NA	18.7	2
PA	Children's	Philadelphia	62	NA	NA
PA	Temple U.	Philadelphia	148	NA	NA
SC	Medical U.	Charleston	99	NA	NA
TN	Baptist Memrl.	Memphis	NA	50.0	2
TN	Vanderbilt	Nashville	80	0.0	7
TX	UTHSC at San Antonio	San Antonio	317	35.8	13
TX	San Antonio Regional	San Antonio	NA	100.0	1
TX	Methodist	Houston	126	43.2	6
TX	St. Paul	Dallas	NA	100.0	1
TX	Baylor	Dallas	180	75.0	2
VA	Fairfax	Falls Church	NA	0.0	1
VA	Medical College Of Va.	Richmond	NA	0.0	3
VA	McGuire VA	Richmond	NA	100.0	1
VA	U. of Va.	Charlottesville	528	30.0	5
WA	Sacred Heart	Spokane	NA	25.0	8
WA	University	Seattle	248	NA	NA
WI	John L. Doyne	Milwaukee	155	0.0	2
WI	U. Of Wisconsin	Madison	162	50.0	1

OXFORD DEVELOPMENT COMPANY
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PITTSBURGH, PA 15219
(412)261-1500

FACSIMILE NUMBER (412)642-7543

TO: PRESIDENT CLINTON
202.456.6703

FROM: DAVE MATTEK

SPECIAL INSTRUCTIONS OR MESSAGES:

ENCLOSED IS A NEWSPAPER ARTICLE
ON THE LIVING DONOR / SPLIT LIVER
TRANSPLANTATION SURGERY I DESCRIBED.

NUMBER OF PAGES INCLUDING COVER PAGE 3

DATE: 2-9-97

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PITTSBURGH POST-GAZETTE ■ THURSDAY, JANUARY 30, 1997

SCIENCE & HEALTH**Toddler gets part
of father's liver****Living-related
transplantation
the first done here**

By Byron Spice

Science Editor, Post-Gazette

Pittsburgh surgeons removed a baseball-sized chunk of a Kentucky man's healthy liver and transplanted it into his gravely ill 17-month-old son Tuesday to perform the area's first living-related liver transplant.

Both Lynn Thomas, 38, of Tompkinsville, Ky., and his son, Haden, were reported doing well yesterday as they recuperated from their respective surgeries.

Because the liver is able to regenerate itself, Lynn Thomas' liver is expected to grow to its former size within a few months. Removed in segments, the portion transplanted into Haden is about the size of the boy's for-

mer liver and will grow as his body does.

More than 500 living-related liver transplants have been performed worldwide. Doctors at the University of Pittsburgh's Starzl Transplantation Institute decided to offer this option because the success rate now equals that of liver transplants from deceased donors. Also, the shortage of donor livers shows no signs of easing.

Haden was born with biliary atresia, an abnormality that prevents bile from draining properly from the liver. Transplantation is the only cure for the condition, which kills

SEE LIVER, PAGE A-3

□ A polio vaccine given to thousands of Pittsburghers was contaminated with a monkey virus that now has scientists worried. **Page A-3**

Tot gets portion of dad's liver; a first here

LIVER FROM PAGE A-1

most patients within two years without treatment.

The boy had waited for more than a year for a donor organ. When intestinal bleeding in November signaled that his condition was deteriorating, both of Haden's parents offered to donate pieces of their own livers.

"It wasn't hard to say 'Let's do it,'" Nanette Thomas said. "Haden needed it. . . . It was hard for both of them to do it, but it was the best thing for all of us."

Both Nanette and Lynn Thomas were evaluated as donors. Lynn Thomas was selected because he and his son share the same blood type.

Dr. Jorge Reyes, director of transplantation at Children's Hospital, said he and Dr. Adrian Casavilla had spent more than a year preparing for the living-related donor program. They plan to offer it routinely to parents whose children need liver transplants.

The donation of part of a liver by parents "is not only very courageous, but it is probably the maximum demonstration of love to their child," Reyes said.

He estimated that perhaps 30 or 40 children now on the waiting list for livers at Children's might be suitable for living-related donation.

Reyes acknowledged that this option could place great pressure on a parent to make a donation.

"But how much pressure is appropriate?" he said. "It only accentuates the fact that these are life-and-death situations."

Only a few years ago, doctors at Pitt hesitated to offer the procedure



Lynn Thomas with his son, Haden, at Children's Hospital.

woman Lisa Rossi said. In Pittsburgh, where the boy was referred for treatment by his Kentucky gastroenterologist, he waited more than a year without success.

The concept of transplanting only a portion of the liver is not new. Pitt surgeons routinely divide donor livers from deceased adults — transplanting a small portion into a child

determine if the Thomases were suitable donors. Radiologists then studied Lynn Thomas' liver closely, estimating the size of each segment and the location of its arteries. Physicians were then able to calculate how much of his liver would have to be removed to replace Haden's.

Casavilla and Reyes performed

Success rates were less than 70 percent, Reyes said. But today, the success rate is about the same as for regular liver transplants — 88 percent at Children's — and donor livers are increasingly hard to come by.

Pitt transplantation officials have long argued that the United Network for Organ Sharing's policies for distributing donor organs have created geographic inequities that penalize large transplant referral centers, such as Pitt.

In Haden Thomas' native Kentucky, the average wait for a donor liver is just 40 days, Pitt spokes-

man says. Patients also are adult recipients — so they can perform two transplants with one organ.

Last year, 12 such operations were performed at Presbyterian University and Children's hospitals.

Though a single organ, the liver is divided into four lobes, each with its own blood supply. One or more segments and their blood vessels can be removed without damaging the remainder of the organ. Such surgery often is performed, for instance, for treating some liver cancers.

Before Tuesday's operations, Dr. Jorge Rakela, Pitt's chief of gastroenterology, supervised testing to

the 12-hour operation to remove 15 percent to 20 percent of Lynn Thomas' liver at Presbyterian. The procedure is meticulous, Reyes said, "so the segment comes out almost perfect."

Reyes then moved to an operating room at Children's, where he transplanted the segments into Haden. That operation was identical to previous operations in which segments of an adult liver have been transplanted to a child.

Doctors expect Lynn Thomas to remain in the hospital for a week. Haden could be discharged in 10 to 14 days.

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FACSIMILE NUMBER (412)642-7543

To: Bruce Lindsey
Assistant to the President and
Deputy White House Counsel

Facsimile Number: 202.456.2983

From: David M. Matter

SPECIAL INSTRUCTIONS OR MESSAGE:

NUMBER OF PAGES INCLUDING COVER PAGE: 9

DATE: September 29, 1996

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David M. Matter

201 UNDERCLIFF ROAD • PITTSBURGH, PENNSYLVANIA 15221

September 30, 1996

President William J. Clinton
The White House
1600 Pennsylvania Avenue
Washington, D.C. 20500

Via Facsimile: 202.456.2983

Dear Mr. President:

As you know, I have always been very active and interested in issues that affect Pittsburgh and the State of Pennsylvania. The largest employer in Pittsburgh is the University of Pittsburgh and the related University of Pittsburgh Medical Center (UPMC). In my real estate and development business, UPMC has been a good client for a number of years. Although I have followed and supported the activities of UPMC for many years, I am not a lobbyist or paid consultant for it. Thus, I wish to bring to your attention an urgent matter that has been pending at the Department of Health and Human Services (DHHS) for over four years which affects UPMC, and more especially patients waiting for organ transplants at UPMC.

UPMC is one of the leading teaching and research hospitals in the country and is a world leader in the field of organ transplantation, especially liver transplantation. As a result of the passage of the National Organ Transplant Act in 1984, the control of donation, allocation and distribution of life-saving organs is placed in the Organ Procurement and Transplantation Network (OPTN) subject to supervision and review by DHHS. The OPTN is operated under contract with DHHS by the United Network for Organ Sharing (UNOS), a private entity. UNOS has 430 members, 276 of which are transplant centers, including UPMC. The other members of UNOS include organ procurement organizations, other medical organizations, 11 voluntary health organizations, and only 6 members of the general public. Decisions at UNOS are made on the "one-member, one-vote" rule. Thus, transplant centers (not the patients) control the decision making.

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UNOS has adopted voluntary policies dealing with the operations of the OPTN (including how organs are allocated to waiting patients), but notwithstanding repeated Congressional criticism of foot dragging, DHHS has never adopted any binding regulations. DHHS began working on regulations in late 1989. In late 1990, UNOS, without DHHS's review or comment, eliminated the STAT priority for allocating livers to the sickest patients wherever located in favor of allocating most livers using the current geography-limited system. UPMC complained in writing to former DHHS Secretary Sullivan in March, 1991, to no avail. Shortly before you took office, DHHS was reportedly prepared to issue regulations adopting the then-existing system based on small geographic areas.

At the urging of Congress and others, your DHHS appointees began looking at the issues again in 1993. DHHS published proposed regulations in September, 1994, seeking comment from the transplant community. The preamble to those proposed regulations specifically asked for comment on the organ allocation policies of UNOS as in effect after the 1990 change and stated that "the present organ allocation policies ... raise difficult issues." UPMC and others submitted comments and proposed alternative allocation systems in December, 1994. Although DHHS stated in the preamble to the proposed regulation, "[t]he process is being initiated to allow the earliest possible adoption of final allocation policies ...", after two years DHHS has still not made any decisions on the issue. UPMC believes that DHHS must move quickly to change the current organ allocation policy because patients are dying while waiting for a liver transplant who would not otherwise die if the existing organ allocation system were changed.

The current liver allocation policy works as follows:

1. Patients are assigned to a Status depending upon their medical condition, as determined by the physician, with Status 1 being the sickest patients (in intensive care with a life expectancy of 7 days or less); Status 2 being patients who are continuously hospitalized. Status 3 are patients who are homebound, and Status 4 patients are the least sick.

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2. Geographically, the United States is divided into 69 organ procurement organization (OPO) service areas which are aggregated into 11 UNOS regions.

3. Livers are allocated first to Status 1 through 4 patients in the OPO service area; if not accepted within the OPO service area, they are allocated to Status 1 through 4 patients in the UNOS region; and finally to Status 1 through 4 patients anywhere in the country outside the region.

The effect of the current policy is to allow a Status 3 or 4 (non-hospitalized) patient to receive a donated liver, instead of using that organ to transplant a Status 1 or 2 patient who, by definition, is near death, simply because the Status 3 or 4 patient is on the waiting list of a transplant center near where the liver is donated. After development of the University of Wisconsin solution almost 10 years ago, a donated liver can be preserved and shipped anywhere in the country by commercial airline (12 to 18 hours) and still be viable for transplantation.

Several viable alternatives to the current system have been proposed by UPMC and others. The proposal made by UPMC would allocate the livers first to a compatible Status 1 in the local OPO service area, then to a compatible Status 1 anywhere in the country; if there is no compatible Status 1 patient, the organ would be offered first to a compatible Status 2 patient in the OPO service area and then to a compatible Status 2 patient anywhere in the country, and so on for Status 3 and 4 patients. This proposal would allocate the livers to the sickest patients in the largest possible geographic area where the organ can be transported and remain in good condition to be transplanted.

Another proposal would allocate donated livers to compatible hospitalized patients (Status 1 and 2) first and then to compatible non-hospitalized patients ("In-Patient First system"). This proposal maintains the "local-region-national" geographic limits of the current system, but insures that patients who have the greatest risk of dying without a transplant, have the first opportunity to receive a compatible liver.

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Consultants for UNOS and for UPMC have developed computer models for liver allocation and have published results from these models for various liver allocation proposals. All of those results have indicated that total deaths among liver transplant patients and recipients are less under the UPMC proposal than under the current system. The UNOS models have indicated that between 30 and 50 lives are saved each year under the UPMC proposal, while the modeling done by UPMC consultants indicates that in excess of 100 lives would be saved per year. The results for the In-Patient First proposal are very similar.

At the present time, there are significant disparities among waiting times for similar liver patients at different transplant centers around the country. The disparities are so great that some patients can wait 4 or 5 times longer for an available organ as similar patients in other parts of the country. The results from the UNOS model and from the UPMC model indicate that the disparity between the waiting times for similarly situated patients at different centers is reduced significantly under the UPMC allocation proposal, and under the In-Patient First system.

The current system has another consequence. The large disparity in waiting times for a liver transplant induces many patients to list at a small transplant center (35 or fewer transplants per year) in hopes of receiving a liver sooner. Approximately 65% of liver transplant centers are in this category. Unfortunately, a 1994 OPTN study showed that the risk of death for transplants at such small centers was 1.6 times greater than the risk of death at centers performing more than 35 liver transplants per year.

Personnel at DHHS are aware of these studies. Nevertheless, there appears to be a genuine reluctance to move forward with the formulation of an organ allocation policy. UNOS, as an organization made up mostly of small transplant centers, seems content to stay with the existing policy since it benefits a large number of the member centers. Although, the UNOS Board recently proposed for comment by its members some minor modifications to the current system, results from the UNOS and UPMC models suggest that such changes, which are now under final consideration by the UNOS Board, are not an improvement over the current system. However, the existing liver

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allocation policy does not benefit patients waiting for liver transplants either. The results of all of the studies indicate that more patients die annually under the existing system than under the UPMC or In-Patient First alternatives, neither of which the UNOS Board is currently considering, and that there is greater disparity of waiting times among patients with similar medical conditions under the existing policy than under either of those proposed alternative allocation systems.

UPMC believes that DHHS should move forward immediately to develop and promulgate the actual organ allocation policy. If DHHS gives more weight to the interests of patients than transplant centers, the new liver allocation system will: (1) allow the patient to choose the transplant center; and, (2) direct the organs to the neediest patients wherever located. The current system is described in comments recently submitted by the University of Nebraska Medical Center at a UNOS forum:

"... the policy mandates that describe liver allocation are not patient-directed, but remain entitlement programs serving transplantation centers rather than patients in a direct and monitorable fashion."

Does DHHS want to endorse this type of policy? DHHS must make the decision on liver allocation policy. UNOS has shown that it cannot, or will not. At present, everything is in limbo, with no reasonable prospects for change, and, by default, the existing system remains in place.

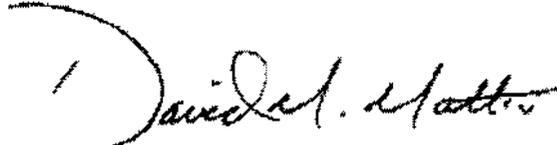
I recognize your tremendously busy schedule and the significant issues that you must face each day. I also know that you maintain a deep and abiding concern for the health and well-being of all of our citizens and are committed to the principles of fairness and a responsive and responsible government. I ask for your assistance in insuring that DHHS moves immediately to adopt regulations for the OPTN that will protect those patients facing imminent death while awaiting transplants and be fair and equitable to all patients.

I have taken the liberty of attaching to this letter a few questions, the answers to which will focus attention on the important

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policy issues that need to be resolved. Thank you very much for your
assistance, and I remain

Sincerely yours,

A handwritten signature in cursive script that reads "David M. Matter". The signature is written in dark ink and is positioned above the printed name.

David M. Matter

Questions

1. What projections or data has DHHS prepared or compiled which compare patient lives saved by Status, pre- and post-transplant, for the current liver allocation system, the UNOS Board proposed changes, the UPMC proposal and the In-Patient First proposal?
2. What projections or data has DHHS prepared or compiled which compare total patient life years saved by Status, pre- and post-transplant, for the current liver allocation system, the UNOS Board proposed changes, the UPMC proposal and the In-Patient First proposal?
3. What projections or data has DHHS prepared or compiled which compare disparities in waiting times by Status by UNOS region, pre- and post-transplant, for the current liver allocation system, the UNOS Board proposed changes, the UPMC proposal and the In-Patient First proposal?
4. If the In-Patient First proposal will save more patient lives, increase total patient life years, and equalize waiting times for patients in a similar medical status across the country when compared to the current system, are there demonstrated negative effects to patients of such proposal which outweigh the benefits?
5. If the UPMC proposal will save more patient lives, increase total patient life years, and equalize waiting times for patients in a similar medical status across the country when compared to the current system, are there demonstrated negative effects to patients of such proposal which outweigh the benefits?
6. DHHS has data which indicate significant differences in risk of mortality for liver patients, pre- and post-transplant, between centers performing more than 35 transplants per year and those performing fewer than 12 transplants. Are there demonstrated medical benefits to patients to encourage patients to choose to be transplanted at high risk centers?

7. Of those centers performing fewer than 35 liver transplants per year, how many are approved for participation in Medicare, Medicaid, VA or other federal government programs for reimbursement for liver transplants?
8. How many centers are performing fewer than 12 liver transplants per year, and are any of those centers approved for participation in Medicare, Medicaid, VA or other federal government programs for reimbursement for liver transplants?
9. Has DHHS established any criteria for determining when the mortality rate at a liver transplant center is unacceptable so that the center may not participate in government reimbursement programs or receive livers for transplant?

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

1995 VOLUME	0-9	10-24	25-49	50-99	100+
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

TESTIMONY OF
THE
NATIONAL TRANSPLANT ACTION
COMMITTEE

BEFORE

THE
DEPARTMENT
OF
HEALTH AND HUMAN SERVICES

ON

LIVER ALLOCATION
AND
ORGAN DONATION

December 10-12, 1996
Bethesda, MD.

EXECUTIVE SUMMARY

National Transplant Action Committee, (NTAC) is a publicly funded non-profit initiative whose mission is to protect and advance the rights and welfare of patients needing organ transplants and their family members. We actively participate in legislative and governmental deliberation that impact our constituents. Although the organization is relatively new, it's principles and directors have years of experience as representatives for organ transplant patients. The organization has a rapidly growing membership.

NTAC supports the Secretary's decision to hold hearings and to promulgate rules on the issue of organ allocation. We believe that the legislative intent of the National Organ Transplant Act clearly places the oversight of the Organ Procurement and Transplantation Network (OPTN) on the shoulders of the Secretary. Despite mandating that the OPTN be a "private non-profit organization" the role of the private contractor is narrowly defined in the legislation. Although the OPTN contractor has argued that the issue before the Department is purely a "medical issue," we believe that the decision of who lives and dies through our national transplant system is truly a public health issue.

Furthermore, despite a 3-year effort to develop a fair public policy on liver allocation the OPTN contractor, the United Network for Organ Sharing (UNOS), has been unable to do so. Instead, recent UNOS actions have instilled tremendous hostility in the public, a lack of trust in the system and panic among waiting liver transplant candidates. Public trust is paramount in our efforts to promote organ donation. We especially

condemn UNOS for its reoccurring attacks on the Department of Health and Human Services and especially its most recent flagrant attempts to stifle public criticism through this hearing process.

With respect to the issue of liver allocation, NTAC supports a system based upon medical necessity versus the current system of local priority. We view the allocation issue as a function of two variables: geography and medical urgency. We believe that the national allocation system should be founded on medical urgency with the most critically ill patients having the highest priority. Based upon the recent report of the UNOS Liver and Intestine Transplant Committee to the UNOS board we believe that a system based upon medical necessity will maximize both utility and equity within the OPTN allocation system. We find UNOS statements regarding the results of their computer modeling on this issue to be biased and misleading. We feel that the UNOS Liver Allocation Model could be an effective tool. However, the manner in which UNOS has utilized this tool is intellectually dishonest.

We feel that a fair allocation system will help in efforts to promote organ donation. For the past few years, UNOS has led an effort to promote organ donation through the "Coalition on Organ Donation." Despite spending millions of dollars the Coalition is unable to show any positive results in increasing organ donation rates. NTAC believes that the key to increasing organ donation is through enhanced professional education and the development of a system providing prompt referral of possible donors to qualified professionals within the Organ Procurement Organizations.

The organ allocation debate and the management of the Organ Procurement and Transplantation Network by UNOS is a great concern to

NTAC. We believe that the actions of the OPTN contractor necessitate a further examination of the National Organ Transplant Act and drastic changes to ensure that the public interest in this arena of health care is protected.

RULE MAKING AUTHORITY

In a letter to Assistant Secretary for Health Philip Lee, UNOS President James Burdick, MD. strongly urged that the Department postpone these liver allocation hearings and that HHS "Issue a public statement reaffirming that both the Department and HRSA "strongly believe that the complex scientific and clinical decisions surrounding these (liver allocation) issues are best made by the transplant community and, in particular, the OPTN board of directors, as a representative body of this community."

This is not the only time that UNOS has challenged the authority of HHS to regulate the OPTN. UNOS filed an extensive complaint with the General Accounting Office regarding many of the provisions of the HHS Request for Proposals for the upcoming OPTN contract. Much of that complaint centered around the authority of HHS to regulate and oversee the operations of the OPTN and UNOS.

Not only is HHS oversight of the OPTN clearly the intent of the National Organ Transplant Act, it is also critical to the interest of the public health. 42 U.S.C. Section 274c places the administration of the National Organ Transplant Act under the jurisdiction of HHS. The law requires the Secretary to "maintain an identifiable administrative unit in the Public

Health Service to administer (the Act) and coordinate with the organ procurement activities under title XVIII of the Social Security Act..." Congressional reauthorization of the Act in 1990 resulted in important statements about the OPTN and the role of the contractor, specifically UNOS. Congress amended the Act to reduce the minimum requirement that must be met by an entity seeking to operate the OPTN. In doing so, it was the intent of Congress "to provide the Secretary with the opportunity to seek out the best possible potential applicants for this critical role. This change...reflect(s) deep concern on the part of the Committee in the manner in which the OPTN has functioned." (Senate Report 101-530, U.S. Code Cong. and Adm. News, p. 4625). Congress also criticized the Secretary for a lack of leadership, "The Committee hopes that the Secretary will take a more personal interest in this important program and will be at the forefront of its success."

Although the Act grants limited authority over medical issues with the OPTN, the legislative history is clear that the oversight of the OPTN is that of the Public Health Service of HHS. The matching of donors and recipients for organ transplantation involves key medical decisions that focus on histocompatibility and the scientific task of matching donors with possible recipients. However, once that has been completed, and a list of possible recipients compiled, it then becomes a public policy question as to who on that list should be given the first opportunity to receive a transplant, who will continue to wait for a transplant, and who will possibly die.

THE "ULAM" COMPUTER MODELING

Although NTAC views this matter as a public health issue, we also

acknowledge the complexities of liver allocation.

In an effort to examine the organ allocation issue, UNOS developed the *UNOS Liver Allocation Model - "ULAM."* This tool facilitates a rational assessment of different allocation algorithms and on key outcome measurements. The ULAM modeling data makes it easy for any public policy maker, regardless of their medical training, to make informed decisions among the various system options.

Despite the usefulness of the ULAM data, NTAC feels that UNOS has used this tool with a bias toward maintaining the status quo. Also, the manner in which UNOS has organized and reported the ULAM data has not been consistent. UNOS model runs report on certain outcome measurements in one report and then on different measurements in later computer runs. This makes it difficult to make comparisons between the different allocation options.

We believe that there are key outcome variables that should be the focus of the public policy decision and the potential benefits of any given allocation option. Total life year measurements such as "*quality adjusted life years*" have been a standard tool used in the overall formulation of health care policy. As reported by Kaplan and Anderson (A General Health Policy Model: Update and Applications; HSR: Health Services Research 23:2, June 1988) life year measurements have been widely used in public policy decisions including Food and Drug Administration evaluation of the effectiveness of new products. The basic model involves the overall evaluation of two competing health care treatment options.

With respect to the ULAM outputs, "total patient life years" and even

“total pre and post transplant deaths” can provide us with an appropriate measurement of the overall benefits of the different allocation options. However, in its deliberations, UNOS has chosen to focus only on post transplant results and has ignored the other part of the equation: the outcome for those patients that do not receive transplants. Without consideration for the patient outcomes for both those who do and do not receive organ transplants we cannot derive the overall health benefits that accrue as a result of our policy decision.

In a recent report entitled “*The Relative Risk of Mortality for UNOS Status 3 Liver Recipients: A Comparison of the Risk Post-Transplant to the Risk on the Waiting List*,” UNOS researcher Erick Edwards concludes: “there is no net survival benefit of (liver transplantation) for Status 3 patients within the first two years following transplantation.” The following table, using recently published UNOS data, illustrates the point at hand:

RELATIVE BENEFIT FROM TRANSPLANTATION
TWO YEARS POST-TRANSPLANT

	survival				net benefit in life years
	with tx		without tx		
	1 yr	2 yr	1 yr	2 yr	
Status 1 patients	69.8%	65.5%	-0-	-0-	1.353
Status 3 patients	80.7%	76.1%	80.7%	76.1%	-0-

UNOS has argued that the slight improvement in survival between Status 1 and Status 3 patients is significant. But, as one can easily see, the

net benefit from transplanting status 1 patients is substantially higher than that of status 3 patients who are essentially receiving no benefit from liver transplantation.

With respect to the matter of equity, UNOS has given virtually no consideration to this issue despite the fact that inequities in waiting times is the heart of the allocation debate. Of the various outcome measurements we believe that the ratio of transplants to individuals on the waiting list is an appropriate marker to analyze the fairness of the different allocation options. Another appropriate measuring tool would be an indicator of those who die waiting for a transplant on a region by region basis.

ULAM RESULTS

Over the course of this debate UNOS has modeled many different allocation options. Based upon the results and our discussions above we support those options that place greater priority on medical status as opposed to geography. Based upon our analysis and review of the UNOS Liver Committee report to the UNOS Board, we believe that the "Inpatient First" policies and the "First Local National" policies show the best overall results and that these options maximize both utility and equity. Our review of these options and a comparison with the current system is included on the next page.

**COMPARISON OF VARIOUS
LIVER ALLOCATION OPTIONS**

TABLE 1

	CURRENT POLICY	FIRST LOCAL NATIONAL
TOTAL PATIENT LIFE YEARS	51,312	51,677
TOTAL PRE & POST TX DEATHS	6242	6105
TRANSPLANTS/PATIENTS LISTED PER REGION (RANGE)	35.29% PTS (H: 65.62% L: 30.33)	6.26% PTS. (H: 43.35% L: 37.09%)
WAITING TIME TO TX OR PRE TX DEATH (RANGE)		
STATUS 1	5.6-3.6 DAYS	26-1.9 DAYS
STATUS 2	10.6-5.0 DAYS	7.6-6.0 DAYS

(SOURCE: ULAM MODELING)

TABLE 2

	CURRENT POLICY	INPATIENT FIRST	FIRST LOCAL NATIONAL
TOTAL PATIENT LIFE YEARS	51,774	53,381	53,690
TOTAL PRE & POST TX DEATHS	7055	6794	6731
AVG. WAITING TIME TO TX STANDARD DEVIATION (REGIONAL)	28.36	11.55	1.59
PERCENT DYING PRE-TX STANDARD DEVIATION (REGIONAL)	4.64	1.92	.53

(SOURCE: CONSAD RESEARCH)

OTHER CONSIDERATIONS

There have been a number of other concerns expressed by UNOS we believe that these concerns only serve to distract from the real issues. Also, these UNOS concerns hold very little if any foundation.

1. "Local use of organs promotes donation." There is no documentation supporting this claim. In fact, we believe that public trust in a fair system is the cornerstone of organ donation.

2. "Greater organ sharing will result in the closure of some centers and will create an access problem for patients." As the enclosed map illustrates, most transplant centers are clustered around large metropolitan areas. We believe that greater sharing may result in consolidation within the transplant community but that it will have no impact on access. In fact, we believe that it may improve access.

3. "Transplanting the sickest patients first is a poor use of donor organs." As illustrated above, status 1 patients derive the greatest benefit from transplantation. We point out that every system that was modeled using the ULAM tool began with transplanting local status 1 patients as the highest priority. The message from competing transplant centers is that status 1 patients are indeed the most important patients to transplant ... unless they are in another part of the country.

ALLOCATION AND MEDICAID

An important issue that has been raised is the impact that greater

sharing will have on the Medicaid population. NTAC President Craig Irwin serves on the Oregon Medicaid Transplant Criteria Committee and has devoted a great deal of time to improving access to transplantation for the Medicaid population.

There is no federal law mandating that states cover any organ transplants under their Medicaid programs. When states do cover organ transplants, often they require that beneficiaries use in-state facilities if they are available and if they are capable of providing the needed services. There are also options for rare cases. If coverage exists, but there are no in-state programs, then the state negotiates with a transplant facility in another state for the provided services. The rate of payment is based upon the reimbursement rate in the beneficiary's home state or the reimbursement is negotiated. There is tremendous latitude. In any event, whenever a Medicaid beneficiary requires services in an out-of-state facility, federal regulations mandate that the beneficiary's home state provide reimbursement for travel, accommodations for the patient, as well as for a necessary "caretaker/companion."

Based upon the federal regulations, and the options that are available to states and beneficiaries, NTAC strongly believes that any consolidation that results from greater liver sharing will not impact the ability of Medicaid beneficiaries to access liver transplant centers. Even if in state facilities are eliminated due to consolidation, then the states must make the appropriate arrangements to provide care with an out of state facility as well as assist in the transportation and accommodations of the patient.

RECOMMENDATIONS

We believe that the Secretary should proceed to publish final liver allocation rules. We further believe that it is in the best interest of the American public to have a system of liver allocation based upon medical necessity as opposed to geographic priority. It is apparent that status 1 patients who receive liver transplants do derive the greatest net benefits from the procedure. By combining these features into our allocation system NTAC believes that utility and equity will both be maximized.

We have offered the following proposal based upon our review of the Liver Committee report to the UNOS board of directors as well as our own assessment of the ULAM data.

NATIONAL TRANSPLANT ACTION COMMITTEE

PROPOSAL FOR

THE ALLOCATION OF LIVERS FOR

ORGAN TRANSPLANTATION

1. Livers should be allocated based upon the medical status of the patients. All patients within a given health status should be eligible for a donated liver before patients in a lower priority status.

2. The allocation order should be as follows:

	LOCAL	REGIONAL	NATIONAL
STATUS 1	1	2	3
STATUS 2	4	5	6
STATUS 3	7	8	9

3. NTAC supports two suitable options for defining geographic boundaries:

a. local = local OPO service area regional = UNOS region

b. local = 500 mile radius from donor regional = 1000 mile radius

4. Criteria should be developed for defining the patient statuses from 1-3. For example, patients who are currently listed in Status 3 but who exhibit esophageal varices or, patients with small intra-hepatic tumors may deserve higher priority status on the waiting list. The goal of the criteria should be to increase use of clinical factors to determine priority on the waiting list instead of patient location (ie. at home, in hospital, etc...). The OPTN should monitor transplant centers for compliance.

5. Transplant center performance standards should be established based upon patient mix and patient mortality. Centers that fail to meet the performance standards should be placed on probation subject to elimination from the network if they fail to meet the established standards.

Distribution of All Current Liver Transplant Programs

by 1995 Volume

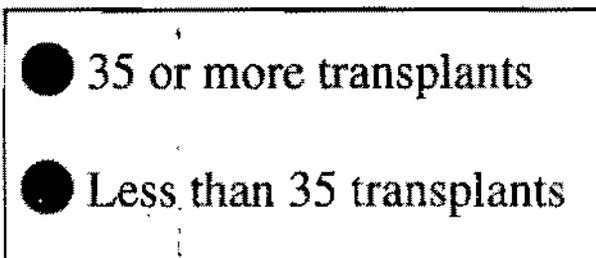


Table 31
Patient Survival Rates at Three Months and at One, Two, Three, and Five Years
October 1987 through December 1994

Liver Transplants

Center Volume	N	3 Month Survival		1 Year Survival		2 Year Survival		3 Year Survival		5 Year Survival	
		%	Std. Err.	%	Std. Err.	%	Std. Err.	%	Std. Err.	%	Std. Err.
0-23	3702	82.2	0.6	76.4	0.7	73.1	0.8	70.4	0.8	65.6	1.0
24-45	3699	85.4	0.6	80.2	0.7	76.2	0.7	73.5	0.8	67.6	1.1
46-92	3893	88.1	0.5	83.1	0.6	80.1	0.7	78.1	0.7	73.7	0.9
93-159	3516	88.6	0.6	82.4	0.7	77.8	0.8	75.3	0.8	70.6	1.0
160+	3590	86.7	0.6	80.1	0.7	76.1	0.8	72.5	0.9	66.5	1.2
Unknown	1564	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.
Overall	19964	85.8	0.3	80.0	0.3	76.3	0.3	73.6	0.3	68.8	0.4

Primary Diagnosis	N	3 Month Survival		1 Year Survival		2 Year Survival		3 Year Survival		5 Year Survival	
		%	Std. Err.	%	Std. Err.	%	Std. Err.	%	Std. Err.	%	Std. Err.
Non-Cholestatic Cirrhosis	10327	86.0	0.4	79.9	0.4	75.9	0.5	72.9	0.5	66.6	0.6
Cholestatic Liver Disease/ Cirrhosis	3484	89.5	0.5	85.4	0.6	83.1	0.7	81.0	0.7	77.6	0.9
Biliary Atresia	1874	84.4	0.9	81.2	1.0	80.3	1.0	78.8	1.0	75.9	1.2
Pulminant Liver Failure	1419	75.9	1.2	70.8	1.3	68.4	1.3	67.6	1.4	64.5	1.6
Metabolic Disease	1052	86.7	1.1	82.1	1.2	80.2	1.3	78.7	1.4	76.2	1.5
Malignant Neoplasms	780	86.4	1.3	66.3	1.8	50.8	2.0	42.1	2.0	33.8	2.2
Other	841	84.3	1.3	79.1	1.5	75.6	1.6	73.2	1.8	71.7	1.9
Unknown	187	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.
Overall	19964	85.8	0.3	80.0	0.3	76.3	0.3	73.6	0.3	68.8	0.4

Source: UNOS Scientific Registry data as of September 7, 1996.

Notes: The survival rates were computed using the Kaplan-Meier method (see Notes on Graft and Patient Survival).

N denotes the number of transplants for which a survival time could be determined.

n.d. denotes not determined due to insufficient sample size.

- denotes none in category.

n.c. denotes not calculated for the Unknown categories.

Table 31
Patient Survival Rates at Three Months and at One, Two, Three, and Five Years
October 1987 through December 1994

Liver Transplants

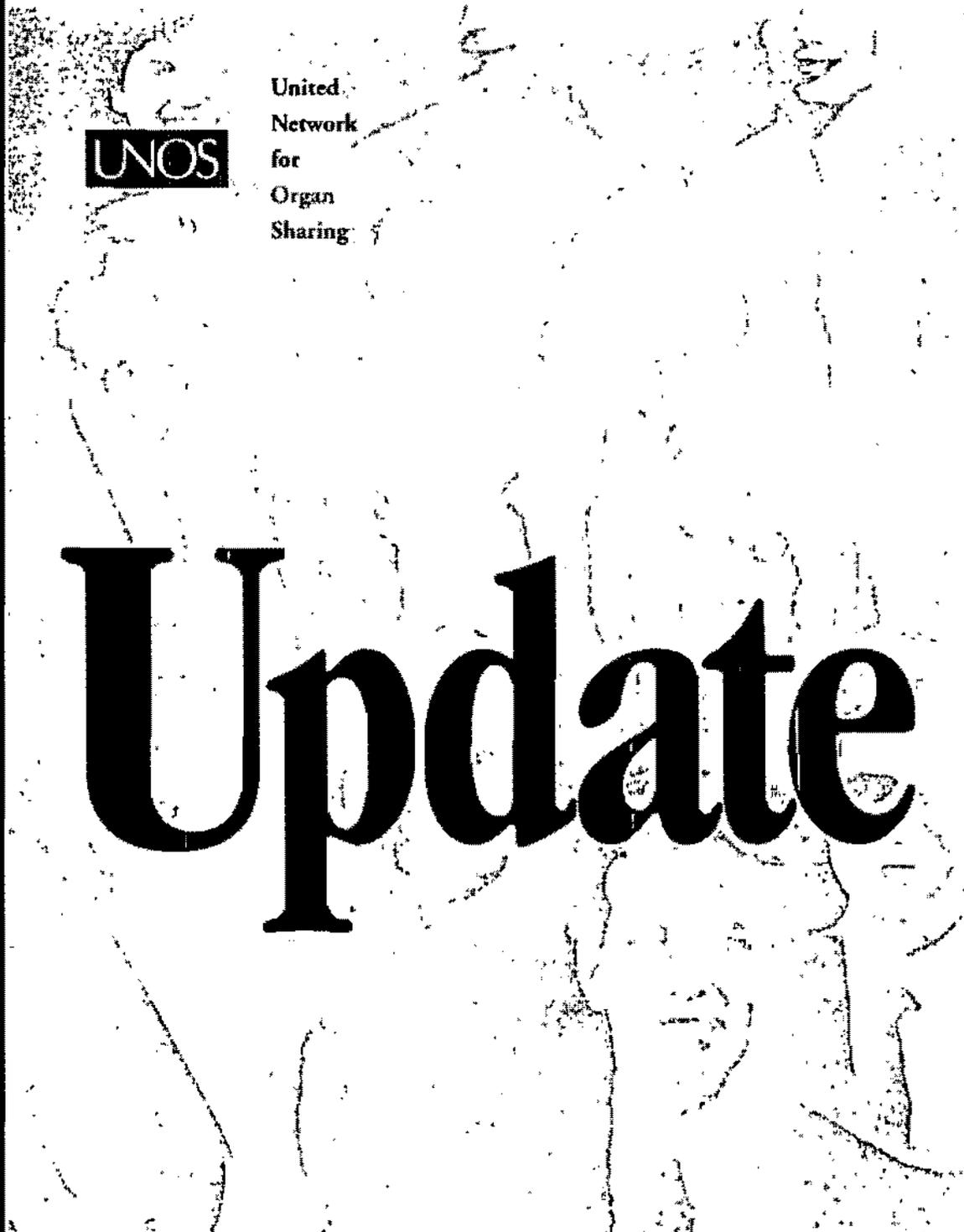
Waiting List Status at Transplant*	N	3 Month Survival		1 Year Survival		2 Year Survival		3 Year Survival		5 Year Survival	
		%	Std. Err.	%	Std. Err.	%	Std. Err.	%	Std. Err.	%	Std. Err.
1	1886	76.2	1.0	69.9	1.1	66.0	1.2	64.1	1.3	n.d.	n.d.
2	2262	88.1	0.7	81.1	0.9	76.7	1.0	73.6	1.2	n.d.	n.d.
3	4611	93.3	0.4	89.2	0.5	85.9	0.6	82.6	0.8	n.d.	n.d.
4	258	93.6	1.5	90.7	1.9	83.6	2.6	82.0	2.7	n.d.	n.d.
Unknown	1071	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.	n.c.
Overall	10088	87.6	0.3	82.2	0.4	78.5	0.5	75.6	0.5	n.d.	n.d.

- * Data are for 1992-1994 only. Current medical urgency status codes for liver allocation are:
- 1 ICU bound, expected to live less than 7 days without a transplant, and meeting at least one of a specific set of other criteria (see UNOS policies).
 - 2 Hospitalized in an acute care bed for at least 5 days or intensive care bound.
 - 3 Requires continuous care.
 - 4 At home.

Source: UNOS Scientific Registry data as of September 7, 1996.

Notes: The survival rates were computed using the Kaplan-Meier method (see Notes on Graft and Patient Survival).

- N denotes the number of transplants for which a survival time could be determined.
 n.d. denotes not determined due to insufficient sample size.
 - denotes none in category.
 n.c. denotes not calculated for the Unknown categories.



UNOS

United
Network
for
Organ
Sharing

Update

JANUARY/FEBRUARY 1997

- *Board Slate Announced*
- *1996 Annual Report Published*
- *Exercise May Help Heart Candidates*
- *Neonatal Donors Needed*
- *Dave Thomas Brings Donation Message to Executives*

W H A T ' S G O I N G O N

The UNOS "What's Going On" and "Who's Going Where" columns are your columns to tell other OPOs, transplant programs, histocompatibility laboratories and other transplant-related organizations about news, activities, resource materials and staff changes you would like to publicize. Please send information to Esther Benenson, Editor, UNOS, P.O. Box 13770, Richmond, VA 23225.

New Members

The UNOS board of directors approved the following facilities for UNOS membership:

Transplant Center

Scottsdale Memorial Hospital-Osborn
Scottsdale, Ariz.
Kidney—Arnold Serota, M.D., director

Transplant Programs

University of Massachusetts Medical Center
Worcester, Mass.
Liver—William Meyers, M.D., director

Shands Hospital at the University of
Florida

Gainesville, Fla.
Heart-Lung—Edward Staples, M.D., and
Barry Bertolei, M.D., directors

Westchester County Medical Center
Valhalla, N.Y.
Liver—James Piper, M.D., director

OPO

LifeCenter Northwest
Seattle, Wash.

Histocompatibility Laboratory

University of Texas Southwestern
Histocompatibility Laboratory
Dallas, Texas
Peter Stastny, M.D., director

General Public Membership

Deborah Surlas, R.N., Aurora, Ill.
Mary Ann Lunde, Miami, Fla.

Membership Total

As of November 13, 1996, UNOS membership included the following:

281	Transplant Centers
54	Independent Organ Procurement Organizations
55	Independent Histocompatibility Laboratories
8	General Public Members
12	Voluntary Health Organizations
29	Medical Professional/Scientific Organizations
4	Consortia
443	Total members

Note: Of the 281 transplant centers, 14 have in-house OPOs and 101 have in-house histocompatibility laboratories.

Of the 281 medical institutions in the United States operating an organ transplant program, there are:

253	Kidney Transplant Programs
120	Pancreas Transplant Programs
120	Liver Transplant Programs
166	Heart Transplant Programs
99	Heart-Lung Transplant Programs
94	Lung Transplant Programs
27	Intestinal Organ Transplant Programs
15	Pancreas Islet Transplant Programs

Donor Astronauts

Tammy Jernigan and Tom Jones have become the first astronauts to sign donor cards in space on a shuttle mission. The astronauts, crew members of the STS-80 Columbia shuttle mission, signed the cards December 2 to draw attention to the ongoing organ and tissue shortage in the U.S.

The idea originated with Anne Conforti, R.N., CCTC, a clinical transplant coordinator at TransLife Organ, Tissue & Transplant Services in central Florida. The event, which took nearly two years to implement after going through lengthy approval steps at NASA, represents a collaborative effort between TransLife, NASA and the Division of Transplantation.

Organ donor cards are currently available to visitors at NASA facilities across the nation. Videos and still photos of the event, as well as commemorative organ donor

cards that were signed in space, will be available. For more information, contact Kathy Driscoll at (407) 897-5560.

Anti-rejection Drugs

SangStat Medical Corporation announced promising results for two of its anti-rejection drugs, generic cyclosporine and thymoglobulin, which they plan to market pending FDA approval.

After two trials, the company's formulation of cyclosporine has been shown to be bioequivalent to Sandoz's drug, a key prerequisite for FDA approval as a generic. If approved, Eli Lilly and Company has agreed to manufacture the drug for SangStat.

A Phase III trial of thymoglobulin, an anti-thymocyte polyclonal antibody preparation derived from rabbits, showed it to be more effective than ATGAM, a similar drug derived from horses, in reversing acute kidney rejection. Call (415) 328-0300, ext. 131, for additional information.

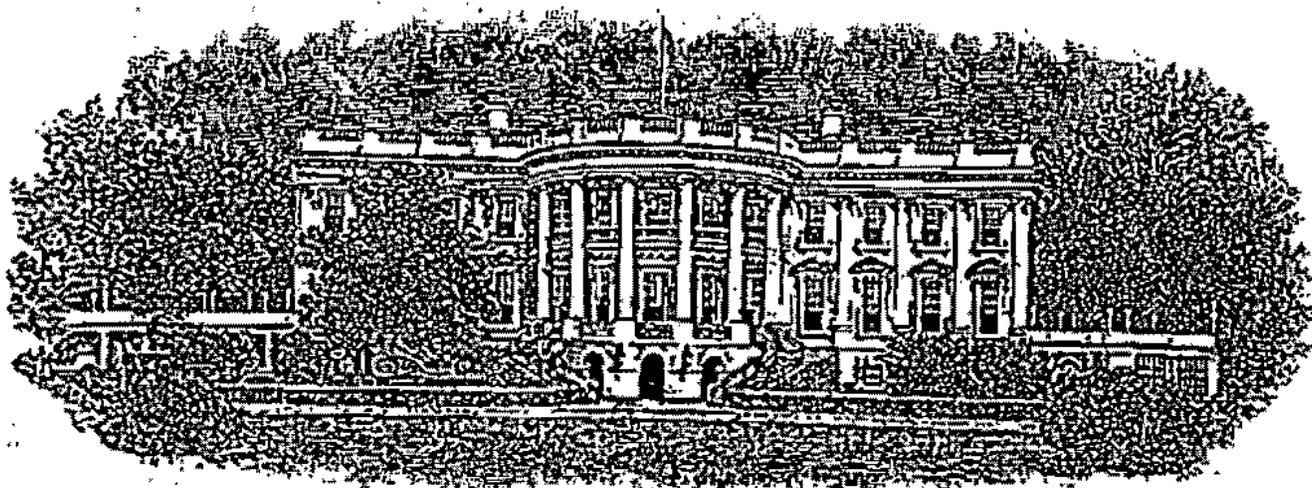
Coroners and Donation

The California General Assembly recently passed a bill to facilitate donation among coroner's cases. The legislation, sponsored by Assemblyman Brett Granlund, of Yucaipa, Calif., would require OPOs to develop a specific protocol to determine how organs can be removed without disturbing other body parts needed for evidence during autopsy. It would also require that coroners provide an explanation as to why permission to donate was denied.

The legislation was initiated through the advocacy efforts of Ron Ranus of Redlands, Calif., whose request to allow his daughter to become an organ donor was refused by the local coroner. Ranus argued that coroners refuse to allow donations to occur out of fear and misconceptions that the procedure will hamper accident and criminal investigations.

According to the bill's supporters, the measure is intended to strongly encourage, but not force, coroners to develop protocols that facilitate donation. Supporters believe the bill will help boost the supply of organs and strengthen cooperation between OPOs and coroners. For more information, call (909) 793-9657.

THE WHITE HOUSE



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Facsimile Transmission Cover Sheet

To: Cathy Mays

Fax Number: 628 B

Telephone Number: 66575

Pages (Including Cover): 2

Comments: Per your email to Sarah...

names & organizations of the folks for

today's 12:30 allocation mtg in Rm 211

Vanderbilt University Medical Center

Vice-Chancellor for Health Affairs

D-3300 Medical Center North
Nashville, TN 37232-2104
(615) 322-3151

April 10, 1997

MEMORANDUM

TO: CHRIS JENNINGS, SARA BIANCHI, AND IRENE YEH

FROM: MARILYN YAGER

RE: LIVER ALLOCATION MEETING ON MONDAY

I just wanted to reconfirm the time, location, and attendees for the liver allocation meeting. We will be coming on Monday, April 14 at 1:00pm to room 216 OEOB. The attendees are the individuals listed below (I understand that you have everyone's clearance information).

ATTENDEES: Watson Bell, Lawyer and Patient Advocate, Arkansas
Dr. Doug Hanto, University of Cincinnati
April Burke, (Lewis-Burke Associates) University of Cincinnati
Dr. Steve Bynon, University of Alabama-Birmingham
Bill Croker, University of Alabama-Birmingham
Dr. Prabhakar Baliga, University of South Carolina
Martha Kendrick (Patton Boggs) University of South Carolina
Dr. Wright Pinson, Vanderbilt University Medical Center
Marilyn Yager, Vanderbilt University Medical Center

ISSUES: Without further guidance from you we plan proceed with the following agenda:

- I. Who we represent (at least 60 regional, mid-size transplant centers)
- II. Why we think we are strong on issues like quality, access (particularly access for Medicaid patients, no pay patients, minority patients, and rural patients), and encouraging greater organ donation.
- III. Why we believe the current UNOS decision making process (with all its faults) should continue, including allowing UNOS to continue to make liver allocation decisions.

NOTE: Please let me know if we have missed the purpose of the meeting, or if you need our response on other issues.