



Health, Education and Human Services Division

B-260630

July 31, 1995

The Honorable Nancy Landon Kassebaum
Chairman, Committee on Labor and Human Resources
United States Senate

The Honorable Edward M. Kennedy
Ranking Minority Member
Committee on Labor and Human Resources
United States Senate

The Honorable Bill Frist
United States Senate

The lack of sufficient organs to provide all waiting patients with a transplant led the Congress to provide for the establishment of a national organ allocation system in 1984. This system also sought to standardize organ allocation practices and ensure that organs are allocated fairly. In an April 1993 report,¹ we found that the Department of Health and Human Services (HHS) and the United Network for Organ Sharing (UNOS)² could not be assured that organs were allocated equitably because they did not monitor and assess specific organ allocation practices. We also noted that some organ procurement organizations (OPO)³ did

¹Organ Transplants: Increased Effort Needed to Boost Supply and Ensure Equitable Distribution of Organs (GAO/HRD-93-56, Apr. 22, 1993).

²UNOS, through a contract with HHS, administers the national Organ Procurement and Transplantation Network established by the National Organ Transplant Act (P.L. 98-507).

³Funded primarily through Medicare reimbursements administered by the Health Care Financing Administration (HCFA), OPOs coordinate organ procurement and allocation. As of November 1994, there were 69 OPOs, which varied widely in the geographic size and demographic composition of their service area as well as in the number of transplant centers and patients served.

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not consider all patients in their areas when allocating organs.

As part of a larger study of organ allocation policies you requested that we provide an update of any deviations from current allocation practices in use. Specifically, you asked that we examine (1) UNOS's progress in monitoring and evaluating the impact of approved variances to the national allocation policy and (2) the extent to which OPOs are not considering all patients waiting in their service areas when allocating organs. You also requested that we provide data on the length of time that patients wait for an organ transplant in different parts of the country.

To determine the status of variances to the national organ allocation policy and use of transplant center-specific waiting lists, we interviewed officials of HHS' Health Resources and Services Administration (HRSA) and UNOS and reviewed documents related to the approval and evaluation of deviations from the UNOS allocation policy. To determine the extent that OPOs were reporting the impact of their variances to UNOS, we reviewed reports submitted to UNOS by OPOs that had variances as of September 30, 1994. To develop information on patient waiting times, we obtained from UNOS an analysis of patient waiting times by OPO and by patient demographics and donor procurement rates and demographics of donors by OPO. We conducted our work from February to May 1995 in accordance with generally accepted government auditing standards.

In summary, we found that although UNOS has procedures for approving and assessing variances to the national organ allocation policy, the impact of these variances on the equitable allocation of organs is unknown. In its first attempt to gather information on the impact of variances, UNOS did not request specific data and the OPOs did not submit necessary data to assess the impact of the variances. At the request of HRSA, UNOS is revising its reporting requirements to improve their ability to assess the impact of the variances.

In 1993, as a result of our report, UNOS established a policy that organs should be allocated using OPO-wide waiting lists; any deviation from that policy needs approval from the UNOS Board of Directors. This policy change has resulted in a significant reduction in the use of transplant center-specific waiting lists from 20 OPOs in 1991 to 3 OPOs in 1995. Exceptions to the policy are based on unique characteristics of the OPO such as geographic size and patient demographics.

The time that patients wait for a kidney transplant varies considerably from OPO to OPO, ranging from a median of fewer than 2 months to almost 3 years.⁴ The median time that patients wait for heart and liver transplants also varies among OPOs but is generally shorter than for a kidney transplant. (See enclosure 1 for more information on kidney patient waiting times).

BACKGROUND

In our 1993 report, we found that neither HHS, UNOS, nor the OPOs were evaluating OPOs' changes to the national organ allocation policy to determine their impact on the equitable distribution of organs or the merit of incorporating these changes into UNOS' allocation criteria. In 1992, while we were conducting our review, UNOS established procedures to approve and monitor these variances.

Effective August 1, 1993, UNOS adopted a policy that defines the local unit for organ allocation as the OPO in most cases. This means that OPOs are to use a single OPO-wide list of patients when making allocation decisions. Alternative local units (ALU)--geographical subdivisions of the OPO that function as distinct areas for organ procurement and allocation--are deviations from single OPO-wide lists that have been recommended by appropriate UNOS committees and approved by the UNOS Board of Directors.

THE IMPACT OF VARIANCES IS UNKNOWN

As stated earlier, in 1992, UNOS adopted procedures for approving the use of variances to the national allocation process and for the OPOs and their area transplant centers to assess the impact of the variances. Additionally, HRSA, through the Organ Procurement and Transplantation Network (OPTN) contract, requires UNOS to monitor variances and assess their impact on organ allocation. However, fulfilling this contract requirement is difficult for UNOS because OPOs are not submitting sufficient information for UNOS to assess the impact that variances have on equitable organ allocation. This is due in part because UNOS did not

⁴To determine variations in waiting times for kidney, heart, and liver transplant recipients we used a UNOS analysis of median waiting times. The patient cohorts include patients added to the kidney, heart, or liver transplant waiting list from 1991 through 1993. The UNOS analysis of median waiting times is as of February 24, 1995.

specifically identify the data OPOs should submit to support their assessments.

As part of its contract to operate the OPTN,⁵ UNOS is to

"closely monitor all variances to allocation policy and report on those variances annually. The report shall include an assessment of the impacts of the different types of variances."

Currently, there are 14 OPOs that were granted variances to the UNOS allocation criteria for one or more organ. Of these, 12 OPOs have variances for kidney allocation, 7 have variances for heart allocation, 1 for lung allocation, and 2 for liver allocation. Ohio, Tennessee, the South-Eastern Organ Procurement Foundation (SEOPF), and UNOS' Region 6, which have sharing arrangements,⁶ also have variances. Three have variances for kidney allocation and one has variances for both heart and liver allocation.

UNOS requested⁷ that OPOs with variances submit reports on a 6-month basis and answer several questions assessing the impact of their variance. Along with the reports, the OPOs are to submit relevant data that assess the impact of the variance and address any organ allocation problems. However, of the 16 OPOs and 4 other entities with variances as of September 30, 1994, only 1 OPO submitted all the requested reports. Of the reports submitted, only 1 OPO provided data that in our analysis was sufficient to substantiate its claim that the variance was meeting its

⁵The most recent contract to operate OPTN became effective September 30, 1993.

⁶A sharing arrangement is an arrangement entered into by two or more OPOs with geographically contiguous service areas to share organs between or among the OPOs. OPOs may distribute organs pursuant to a sharing arrangement with prior approval by the UNOS Board of Directors. Organs must be distributed within the sharing area on the basis of a common patient waiting list unless an appropriate alternative local unit for the area is approved by UNOS.

⁷Currently, HHS characterizes OPTN policies as voluntary guidance for OPOs; consequently OPOs can choose to comply or not comply with these policies.

intended goal. We were unable to obtain from UNOS the number of patients affected by these variances.⁸

UNOS, at the request of HRSA, has recently taken actions to obtain more useful information for assessing the impact of variances. First, due to concerns that the 6-month reporting interval did not allow for enough time to make an assessment of the impact of the variance, in March 1995, the UNOS policy changed to request that OPOs submit data at 1-year intervals or more frequently upon request. Second, UNOS will be specifying more clearly the data elements that should be submitted to support the OPO's assessment of the impact of the variance. Data elements under consideration include among others, patient survival, waiting time, minority patients transplanted, and highly sensitized patients transplanted. In the past, OPOs had discretion on what data, if any, they provided to support the benefits of the variance.

MORE OPOs USE OPO-WIDE PATIENT LISTS
WHEN ALLOCATING ORGANS

UNOS has made great strides in reducing the number of OPOs that do not use a list of all patients when making allocation decisions. In 1991, 20 of the 68 OPOs used allocation systems that did not consider all patients within their service areas when allocating organs. In our 1993 report, we recommended that this practice be eliminated because it was inconsistent with federal law if subdivisions of the OPO waiting list were created for reasons other than medical criteria.

Currently three OPOs have UNOS approval to use ALUs or partial lists of patients waiting within the OPO service area. These OPOs have ALUs for one or more organs.⁹ One OPO was granted an ALU because the OPO is made up of three noncontiguous geographical areas as much as 500 miles apart. The OPO argued that using one list for these three areas would be detrimental to organ quality and distribution,

⁸UNOs officials stated that they have had difficulty calculating the number of patients affected by these variances. For example, some variances apply to an extremely small populations of patients on a transplant center's waiting list and some variances have been in place for only part of the reporting period.

⁹Additionally, three states and SEOPF have approved ALUs.

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cost-effectiveness, organ procurement, and patient care. Another OPO was granted an ALU because of its large population and changing patient referral patterns, number of states served, and the number of transplant centers. The third OPO was granted an ALU based on its size and the distance between donors and patients. In addition, one of the regions within the OPO has a large minority patient population and the OPO was concerned that its ability to procure organs from minority donors would suffer if it used a single OPO-wide waiting list.

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We obtained comments from HRSA and UNOS on a draft of this correspondence. They generally agreed with our findings and provided technical comments, which we incorporated as appropriate.

We will send copies of this correspondence to the Administrator of the Health Resources and Services Administration and make copies available to others upon request.

If you or your staff have any questions concerning this information, please call Rose Marie Martinez, Assistant Director, at (202) 512-7103 or Roy Hogberg at (202) 512-7145. Other contributors to this correspondence are Susan Lawes and Brenda James Towe.



~~for~~ Mark V. Nadel
Associate Director
National and Public Health Issues

WAITING TIMES VARY GREATLY AMONG OPOs

Considerable difference exists among the OPOs in their median patient waiting times. The median number of days from being placed on the UNOS waiting list to kidney transplantation was 602 days.¹ However, the median waiting times ranged from 85 days at one OPO to 965 days at another. Although patients generally wait a shorter time for liver and heart transplants, considerable variation in the time that patients wait for these organs also occurs among OPOs. The national median waiting time for patients waiting for a heart transplant was 219 days whereas the median waiting time by OPO ranged from 58 to 605 days.² Similarly, for liver transplant patients the national median waiting time was 102 days with a median waiting time of from 23 to 368 days among OPOs.

Table 1.1 identifies OPOs with median waiting times for kidney patients that were below the national median waiting time and selected OPO characteristics. Table 1.2 shows these data for OPOs with median waiting times above the national median waiting time. Variations in waiting times among OPOs may be affected by various factors, including the number of patients waiting, the number of organs donated, and certain patient characteristics.

¹UNOS provided us with an analysis of median waiting times based on a patient waiting list cohort that includes only those patients added for kidney transplant during 1991 through 1993. The UNOS analysis of median waiting times is as of February 24, 1995.

²The median waiting time for the Organ Donor Center of Hawaii is 0 days. For the 3-year period, nine patients were added to the OPO's waiting list and nine patients were transplanted.

Table 1.1: Median Waiting Times for Kidney Patients and Selected Characteristics for OPOs Below the National Median Waiting Time

Organ procurement organization	Patients added		Cadaveric Kidneys donated		Kidneys per million population	Kidneys to patients	No. of transplant centers	Median days waiting
	Percent African		Percent African					
	Total	American	Total	American				
Oregon Health Sciences University Hospital (Portland OR)	330	5%	400	2%	113	1.21	1	85
Lifelink of Southwest Florida (Fort Meyers, FL)	99	16%	135	4%	138	1.36	1	112
Lifelink of Florida (Tampa, FL)	436	23%	486	7%	191	1.11	2	129
Florida Hospital (Orlando, FL)	247	25%	363	5%	172	1.47	1	147
Kentucky Organ Donor Affiliates (Louisville, KY)	397	18%	439	7%	133	1.11	3	168
Life Connection of Ohio (Maumee, OH)	241	26%	249	6%	101	1.03	2	176
University of Miami OPO (Miami, FL)	313	20%	518	16%	113	1.65	2	222
Intermountain Organ Recovery System (Salt Lake City, UT)	287	0%	298	0%	137	1.04	4	237
Life Resources Regional Donor Center (Johnson City, TN)	75	3%	96	0%	151	1.28	1	243
Ohio Valley Lifecenter (Cincinnati, OH)	267	37%	243	10%	132	0.91	3	246
Strong Memorial Hospital (Rochester, NY)	270	16%	263	7%	111	0.97	2	251
South Texas Organ Bank, Inc. (San Antonio, TX)	543	17%	331	5%	116	0.61	3	254
OPO of Albany Medical College (Albany, NY)	227	12%	186	2%	87	0.82	1	260
Nebraska Organ Retrieval System (Omaha, NE)	219	7%	198	3%	127	0.90	4	261
Golden State Transplant Services (Sacramento, CA)	253	14%	222	10%	130	0.88	2	268
New Mexico Donor Program (Albuquerque, NM)	209	4%	204	0%	135	0.98	2	290
Lifeline of Ohio OPA (Columbus, OH)	653	23%	388	11%	147	0.59	2	294
Sacred Heart Medical Center (Spokane, WA)	108	1%	98	0%	102	0.91	2	297
Arkansas Regional Organ Recovery Agency (Little Rock, AR)	268	32%	222	8%	162	0.83	3	311
Nevada Donor Organ Recovery Service (Las Vegas, NV)	160	18%	145	4%	121	0.91	3	314
Virginia's Organ Procurement Agency (Midlothian, VA)	160	18%	152	7%	100	0.95	2	327
Midwest Organ Bank, Inc. (Westwood, KS)	481	15%	500	6%	106	1.04	6	330
Lifegift Organ Donation Center (Houston, TX)	918	25%	660	10%	102	0.72	7	340
Colorado Organ Recovery Systems, Inc. (Denver, CO)	447	10%	385	5%	105	0.86	5	354
Medical College of Georgia Hospital (Augusta, GA)	183	61%	173	22%	88	0.95	1	385
Center for Organ Recovery and Education (Pittsburgh, PA)	1346	15%	732	5%	166	0.54	5	387
Indiana Organ Procurement Organization (Indianapolis, IN)	514	17%	452	5%	95	0.88	4	406
Hartford Hospital (Hartford, CT)	224	26%	132	9%	85	0.59	1	409
Iowa Statewide OPO (Iowa City, IA)	328	7%	244	1%	95	0.74	3	416
Shands Hospital (Gainesville, FL)	490	36%	314	11%	116	0.64	3	417
Northwest Organ Procurement Agency (Seattle, WA)	571	8%	451	2%	89	0.79	4	434
Southwest Organ Bank (Dallas, TX)	1046	30%	811	11%	122	0.78	8	446
Louisiana Organ Procurement Agency (Metairie, LA)	581	56%	518	22%	123	0.89	6	448
Oklahoma Organ Sharing Network (Oklahoma City, OK)	452	17%	274	3%	142	0.61	4	457
Carolinas Medical Center (Charlotte, NC)	218	41%	144	19%	81	0.66	1	459
Mid-America Transplant Association (St. Louis, MO)	596	35%	485	17%	120	0.83	5	461
University of Wisconsin Hospital and Clinics (Madison, WI)	768	11%	420	0%	160	0.55	3	476
South Carolina Organ Procurement Agency (Charleston, SC)	392	70%	294	16%	91	0.75	1	523
Alabama Organ Center (Birmingham, AL)	1014	57%	514	21%	121	0.51	2	531
Froedtert Memorial Lutheran Hospital (Milwaukee, WI)	433	27%	256	9%	118	0.59	4	533
Mississippi Organ Recovery Agency (Jackson, MS)	152	78%	116	19%	46	0.76	1	546
Organ Donor Center of Hawaii (Honolulu, HI)	111	2%	95	0%	86	0.86	1	573
Upstate New York Transplant Services (Buffalo, NY)	138	28%	122	5%	78	0.88	4	587

Note: The number of transplant centers (both inside and outside the OPO's service area) are those that listed patients with the OPO.

Source: The median days waiting, patients added, cadaveric kidneys donated, and percentage of African-Americans is based on a UNOS analysis of OPO data. The patient cohort used in this analysis includes patients added to the kidney transplant waiting list from 1991 through 1993. The analysis of median waiting times is as of February 24, 1995. The number of transplant centers and the OPO population to compute kidneys per million population is from Organ Transplants: Increased Effort Needed to Boost Supply and Ensure Equitable Distribution of Organs (GAO/HRD-93-56, Apr. 22, 1993), pp. 55-57.

Table 1.2: Median Waiting Times for Kidney Patients and Selected Characteristics for OPOs Above the National Median Waiting Time

Organ procurement organization	Patients added		Cadaveric kidneys donated		Kidneys per million population	Kidneys to patients	No. of transplant centers	Median days waiting
	Percent African		Percent African					
	Total	American	Total	American				
Lifesource, Upper Midwest OPO (Minneapolis, MN)	1017	5%	733	1%	126	0.72	9	810
New Jersey Organ and Tissue Sharing (Springfield, NJ)	743	36%	508	15%	85	0.68	4	858
Mid-South Transplant Foundation (Memphis, TN)	276	60%	164	18%	127	0.59	4	887
Donor Network of Arizona (Phoenix, AZ)	569	8%	320	3%	87	0.58	6	890
Tennessee Donor Service (Nashville, TN)	642	28%	376	6%	104	0.59	5	891
University Hospital of SUNY at Stony Brook, NY	133	25%	100	10%	38	0.75	1	898
North Carolina Baptist Hospital (Winston-Salem, NC)	206	30%	148	16%	83	0.72	1	899
California Transplant Donor Network (San Francisco, CA)	2630	15%	1021	5%	120	0.39	5	720
New England Organ Bank (Newton, MA)	1764	13%	962	2%	85	0.56	14	728
Lifenet Transplant Services (Virginia Beach, VA)	562	55%	332	35%	121	0.59	5	733
Regional Organ Bank of Illinois (Chicago, IL)	1923	40%	1012	26%	91	0.53	9	751
Transplant Resource Center of Maryland (Baltimore, MD)	968	48%	377	23%	128	0.39	3	751
Lifeink of Georgia (Atlanta, GA)	791	49%	450	18%	104	0.57	4	766
Washington Regional Transplant Consortium (Falls Church, VA)	915	53%	420	32%	107	0.48	8	771
UCSD Medical Center (San Diego, CA)	689	16%	380	6%	146	0.55	3	790
Regional OPA of Southern California (Los Angeles, CA)	2701	17%	747	6%	61	0.28	15	810
Organ Procurement Agency of Michigan (Ann Arbor, MI)	1537	37%	956	12%	103	0.62	10	811
Delaware Valley Transplant Program (Philadelphia, PA)	1915	29%	1143	13%	113	0.60	10	867
Lifebanc (Cleveland, OH)	791	36%	458	16%	110	0.58	5	965
Carolina Organ Procurement Agency (Greenville, NC)	561	58%	289	18%	88	0.52	3	b
New York Regional Transplant Program (New York, NY)	2477	34%	869	24%	85	0.35	8	b
Auxilio Mutuo Hospital (Hato Rey, PR)	135	2%	26	8%	7	0.19	1	b

Note: The number of transplant centers (both inside and outside the OPO's service area) are those that listed patients with the OPO.

^bUNOS could not compute the median waiting time because the number of patients transplanted is smaller than the number of patients still waiting.

Source: The median days waiting, patients added, cadaveric kidneys donated, and percentage of African-Americans is based on a UNOS analysis of OPO data. The patient cohort used in this analysis includes patients added to the kidney transplant waiting list from 1991 through 1993. The analysis of median waiting times is as of February 24, 1995. The number of transplant centers and the OPO population to compute kidneys per million population is from Organ Transplants: Increased Effort Needed to Boost Supply and Ensure Equitable Distribution of Organs (GAO/HRD-93-56, Apr. 22, 1993), pp. 55-57.

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