

Organ Allocation for Transplantation in the USA and Korea: The Changing Roles of Equity and Utility

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Realizing the promise and managing the success of organ transplantation requires the creation of unique institutions. An Organ Procurement and Transplant Network (OPTN) must be capable of increasing the supply of cadaver donor organs, of allocating those organs properly to recipients with due consideration for equity and utility, and of using scientific data to improve the system for the good of society. The OPTN should answer to the public and should expect public support. Both in the United States and in Korea major changes in deceased donor organ procurement and allocation are in progress. In the United States change takes the form of a renewed emphasis on achieving equity in kidney allocation without significantly sacrificing transplant graft or patient survival and the first ever use of purely objective, statistically evaluated criteria for liver allocation. In Korea where the OPTN is only four years old, change takes the form of a new brain death law and the creation of that country's first organ procurement organizations. In both countries, success in meeting the transplant needs of their populations will ultimately depend on the support of society and the cooperation of the entire medical community.

Key Words: Transplantation, organ allocation, organ procurement, kidney transplantation, liver transplantation, organ donation

The Organ Procurement and Transplant Network (OPTN) of the United States is run by UNOS, the United Network for Organ Sharing. From UNOS' birth in turbulent times it has survived troubled periods including the era of the "transplant wars" to become an effective and increasingly efficient organ allocation network for

the people of the United States. The much more recently developed Korean Network for Organ Sharing (KONOS) is experiencing some of the same difficulties that characterized the formative years of UNOS. It may be instructive therefore, to review and contrast the recent history of the two organizations. After two decades of transplant system development, center-related factors including transplant center quality have been recently relegated to a secondary place behind several patient-related factors in the United States system. There has been an increased emphasis on equity and a corresponding decline in emphasis on utility as seen from the transplant recipient point-of-view. In the Korean system, on the other hand, gaining acceptance of the recent brain death law and the development of effective organ procurement organizations (OPO's) to facilitate cadaver donor transplantation remain a high priority. The evolution of the two organizations will be compared and contrasted in this article. In each case, a strong working relationship between the transplantation community and the government was necessary for OPTN development. The confidence of the society at large and the support of the larger medical community have been key elements in the evolution of both organizations.

BRIEF HISTORY OF UNOS

2004 marks the 50th anniversary of the first successful kidney transplant in man performed by Dr. Joseph Murray of Boston in 1954. However, it was not until a decade later that it became clear that genetic matching could improve graft survi-

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val for cadaveric donor kidney transplantation. At that time the few functioning kidney transplant centers often found that they had no suitable recipient for every cadaver donor organ that came available. Both to improve transplant outcomes and to avoid wastage of a precious human resource, techniques were developed to extend the survival of preserved kidneys and to share them successfully between centers. In 1969 the Kidney Disease and Control Agency of the US Public Health Service awarded a contract to the South-Eastern Regional Organ Procurement Program, to share organs among a transplant consortium of 8 programs in 4 states and the District of Columbia.

Under the surgical direction of Dr. David Hume, the scientific direction of Dr. D. Bernard Amos and the administrative direction of Mr. Gene A. Pierce the South-Eastern Regional Organ Procurement Program expanded rapidly to 18 members in a 6 state area. In 1975 it became known as the South-Eastern Organ Procurement Foundation (SEOPF) and 2 years later, in January 1977 it established the United Network for Organ Sharing (UNOS) to permit computer system registration of potential recipients for kidney sharing throughout the entire United States.¹ Participation was voluntary but any kidney transplant program in the country could choose to access the computer registry, use the matching program, and thus better utilize cadaver donor kidneys. Utilization of the UNOS match program had become so wide-spread by 1982 that a Kidney Center, staffed 24 hours a day every day of the year, was established to run the computer algorithm and help centers locate recipients for their cadaver donor kidneys and other organs. The Kidney Center helped to arrange transportation for the organs, assisted teams with travel for organ procurement, and established a system to meet the urgent needs of very sick patients. As its functions expanded from kidneys alone to hearts and livers as well it was renamed the "Organ Center" in 1984. That same year UNOS was incorporated as a private, non-profit, voluntary, medical, scientific and educational organization to run the computer registry of potential transplant recipients and to assist in the placement of cadaver donor organs. In addition to its goal of improving the organ procurement, distribution and transplant systems

for the United States, UNOS began to systematically gather and analyze data on organ procurement and transplant outcomes, thereby creating the database which has fundamentally changed the course of transplantation in the United States. A federally mandated Task Force on Organ Transplantation produced the recommendation that the United States government create and operate a national Organ Procurement and Transplantation Network to establish procedures and policies for effective, equitable organ transplantation throughout the nation. UNOS was awarded the first federal contract to establish and operate the OPTN in 1986 and has held that contract for the subsequent 18 years to the present. In addition, the Scientific Registry of Transplant Recipients (SRTR) was maintained by UNOS under contract with the US Health Resources and Services Administration until October 2000 when the contractor became The University Renal Research and Education Association of Michigan. Both the OPTN and the SRTR contractors continue to work closely together to improve transplantation in the United States.

UNOS has divided the US into 11 geographic regions for administrative and sharing purposes. (Fig. 1) It should be apparent that the regions are uniform neither in size nor in population. The same could be said for the transplant centers, organ procurement organizations (OPO's) and

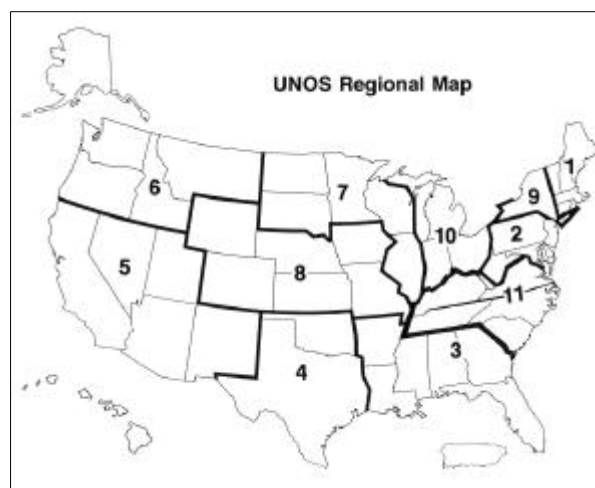


Fig. 1. For purposes of administration of the OPTN, the US was divided first into 8 and subsequently into 11 regions based upon historical organ sharing arrangements in existence at the time UNOS was created.

histocompatibility testing laboratories that provided critical services to the OPTN. The disparities in geographic and population size of the UNOS Regions have led to disagreements about the proper allocation of organs within local and regional units of UNOS, disagreements which in the early years became quite heated and were termed in the lay press the "transplant wars". Not only did transplant centers battle one another on the field of public opinion, but also they resorted to suing each other in Federal Court to achieve their center-specific goals. The Congress of the United States and subsequent versions of the OPTN contract have made it abundantly clear that the allocation of a scarce cadaver donor organ is to be made to a patient and not to a surgeon, a transplant center, a local OPO or a UNOS region. Establishing a proper balance between equity and utility has been the challenge and goal of the UNOS Committees and Board ever since the inception of the organization. In recent years membership in the national OPTN is no longer a voluntary proposition for transplant centers. Centers must join the OPTN and abide by its rules or risk losing their eligibility to participate in the federal Medicare and Medicaid programs. The public has an important, abiding interest in the rules adopted by the OPTN: If every member of the public is asked to donate organs then all citizens should be eligible to receive them as well. Cadaver donor organs for transplantation are regarded as a public good, a scarce human resource, and not the possession of surgeons, programs, centers or regions. This public mandate together with new scientific data from the transplant registry has led recently to a changed understanding of the roles of equity and utility in the United States' system of organ allocation as outlined below.

BRIEF HISTORY OF KONOS

The first renal transplantation in Korea was done in 1969 from a living donor. For the next 10 years until 1979, when the first operation of renal transplantation using a cadaveric donor was performed, all organs for transplantation were donated by living persons. Since then, the Korean

Society for Transplantation, the Korean Medical Association and doctors interested in transplantation have expended great efforts to obtain legislation of a brain death law by the Korean government. A Seoul "Declaration of Brain Death" was drafted and approved by the members of the Asian Transplant Society who participated in the 4th Asian Transplant Congress in 1994.

The main reason for promoting the legislation of a brain death law in Korea was to legally perform cadaveric organ transplantation. During the 20 years until 2000, cadaveric organ transplantations including kidney, liver, pancreas, heart and lung were successfully performed by many leading transplant surgeons without legislation. This raised many social and legal issues and emphasized the necessity of a brain death law. Another reason to seek the brain death legislation was the serious donor shortage made apparent by the increasing number of transplant centers with ever longer transplant patient waiting lists. During this time, less than 10% of the transplanted organs were from cadaveric donors. This might seem to be a small proportion of donor organs, but every transplant center was eager to get an organ from any donor, living or cadaveric, to save the life of an end-stage patient. In this respect, organ allocation from cadaveric donors became a very important issue but there was no organization to manage the problem.

Since there was no nationwide network or data bank to maintain transplant waiting lists, the donated organ from a brain dead donor sometimes could not find an available recipient and eventually had to be discarded. The transplant center that treated the brain dead donor used the procured organs for the patients waiting in the donor hospital. Sharing of the organ with other centers was possible only if there was no available recipient in the donor hospital.

To eradicate commercial donors in the transplantation field was yet another reason to legislate organ transplantation laws. What the transplant centers and doctors did was to campaign for brain death legislation. They conducted public forums about brain death to familiarize the public with the issue and to show that legislation was necessary to save the lives of people, possibly family members, with end stage disease. Praiseworthy

stories of organ donation were reported in newspapers or broadcasted on television which turned public opinion in favor of organ donation and transplantation. The majority of Koreans began to see the value of cadaveric organ donation and the need for a brain death law.

To solve these problems, laws of organ transplantation including brain death were passed by the National Assembly in 1999 and became effective in 2000. As the laws became effective, an organization that could coordinate all of the complicated procedures and gather data about organ transplantation became necessary. A national organization named the "Korean Network for Organ Sharing" (KONOS) was established by the government under the Ministry of Health and Welfare modeled after UNOS and Eurotransplant. Now, all Korean transplant policies and procedures would be approved by KONOS. To facilitate the effective organ transplantation, KONOS licensed and grouped transplant hospitals into four categories: Hospital for organ transplantation, hospital for declaring brain death, hospital for caring for the brain dead donor and procurement (HOPO) and hospital for accepting the patient waiting for transplantation. Some centers accommodate all four of these functions but others do only one or two according to their capability.

Since KONOS was founded and operated by the government, the organization was given a very limited budget. Korea has no legal basis to establish a local Organ Procurement Organization in each region, so, hospitals licensed as HOPOs have to combine their hospital transplant center functions together with operation of the local Organ Procurement Organization. Because there was no support from KONOS or the government many unexpected things happened especially in organ donation after starting the KONOS system.

An increasing number of brain death donors was anticipated after the KONOS system was established, but instead the number of cadaveric liver donors actually decreased (Table 1). The main reason for this decline was felt to be the increased burden on the HOPO to fulfill the reporting requirements and the complicated processes of allocation of the early KONOS system. In contrast, there was no incentive to perform the hard work of donor care. This diminished the desire to manage the brain death donor and depressed the mood of the donor care team. Many centers actually refused to take care of such donors, and this eventually resulted in a reduction of the number of brain death donors. Recently, incentives such as allocation of one kidney to a recipient of the donor HOPO, have been instituted to encourage hospitals to increase the number of brain death donors (Table 2).

Another problem faced by KONOS was the rigid brain death criteria written into the law which sometimes interfered with the declaration of brain death. From the beginning of KONOS and continuing until now brain death is declared by careful examination and testing by two specialists according to criteria at 6 hours intervals, and this result must be re-evaluated by the brain death evaluation committee of each HOPO, a process which takes many hours, sometimes overnight, after the declaration of brain death. To get a flat EEG is another obstacle for the final decision of brain death. Sometimes the heartbeat stops during the extended process and organ procurement is no longer possible. Brain perfusion studies or other confirmative studies are not permitted as a substitute for a flat EEG. Although these rigid criteria may have been necessary to strictly regulate cadaveric transplantation at the beginning, they have resulted in more losses than gains.

Table 1. Liver Transplantation (LTP) in Korea within the KONOS (Korean Network for Organ Sharing) System

YEAR	2000	2001	2002	2003
Donor Type	LD/CD*	LD/CD	LD/CD	LD/CD
Number of LTP Procedures	186/42	286/37	334/27	364/50
Number of LTP Hospitals and Donor Source Used	13/6	11/6	10/7	8/7
Number of Hospitals Performing >10 Transplants per Year	3	6	6	5

*LD, living donor liver transplant; CD, cadaver donor liver transplant.

Table 2. Kidney Transplantation (KTP) in Korea within the KONOS (Korean Network for Organ Sharing) system

YEAR	2000	2001	2002	2003
Donor Type	LD/CD	LD/CD	LD/CD	LD/CD
Number of KTP Procedures	557/125	690/101	669/70	541/111
Number of KTP Hospitals	50	44	41	38
Number of Hospitals Performing >30 KTPs per Year	6	7	7	6
Number of Hospitals performing <10 KTPs per Year	34	25	26	23
Number of Brain Dead Donors	53	52	36	67

LD, living donor kidney transplantation; CD, cadaver donor kidney transplantation.

Table 3. The Role of U.S. Center Transplant Volume in Liver Graft Survival at 1 Year and 5 Years

Yearly center volume	1 year survival			5 year survival		
	N	%	SE	N	%	SE
0 - 9	164	82.1%	0.3%	241	62.7%	3.2%
10 - 19	499	77.1%	1.9%	477	67.7%	2.2%
20 - 34	1,308	81.7%	1.1%	1,191	63.8%	1.4%
35 - 56	1,753	82.1%	0.9%	1,758	65.3%	1.2%
57 +	5,111	80.2%	0.6%	4,120	63.3%	0.8%
Total of all	8,835	80.6%	0.4%	7,787	64.1%	0.6%

Source, OPTN/SRTR Data as of August 1, 2003.

Until last year, the number of brain death donors is about 60 cases every year and this number is far less than Korea had before KONOS in 1999.² However, Korea has realized some positive results from the creation of KONOS. Two of these are the increased number of organs that are procured from each donor and the increased rate of organ sharing among KONOS transplant centers after procurement. Absence of commercial donors is another benefit. Korea, like nearly every other transplanting country in the world has a serious imbalance of donors as compared to recipients even after the start of the KONOS system. The nationwide waiting list of potential organ transplant patients and data about transplantation are additional benefits since the creation of KONOS.

Problems that KONOS must now solve are how to increase brain death donors, and how to allocate scarce livers and hearts among the many patients who need them. Only 5-6 centers do more than 10 cases of liver transplantation per year (Table 1). However, neither in the case of livers

(Table 3) nor in the case of kidneys (Table 4) does transplant center volume have a significant impact on graft survival at 1 and 5 years. These are problems that result from the increasing success of transplantation of life-saving organs from deceased donors. The nearly two decades of experience with these problems in UNOS may suggest some possible approaches to solving them.

LESSONS LEARNED

During the early days of transplantation when there were few potential recipients the focus of organ sharing was on finding a suitable unsensitized recipient to prevent wastage of organs. As transplantation outcomes have improved and the demands of organ failure patients for replacement organs have increased exponentially, the emphasis has shifted to proper allocation of a scarce resource. Since vital human organs for transplantation are life-saving and in short supply, the

Table 4. The Role of U.S. Center Transplant Volume in Kidney Graft Survival at 1 and 5 Years

Yearly center volume	1 Year			5 Years		
	N	%	± S.E.	N	%	± S.E.
0 - 12	246	90.6	1.9%	412	63.6	2.6%
13 - 28	1,186	89.3%	0.9%	1,558	66.9%	1.3%
29 - 47	2,185	89.2%	0.7%	2,233	66.6%	1.0%
48 - 81	3,684	88.1%	0.5%	3,730	63.5%	0.8%
82 +	8,722	88.7%	0.3%	7,291	66.5%	0.6%

Source, OPTN/SRTR Data as of August 1, 2003.

principles and rules used for allocation of solid organs arouse heated ethical debates: Should the rules give priority to centers or to patients, to science or to politics, to utility or to equity, to individual good or to the common good of the entire group? Oftentimes the answers to these questions require balancing priorities. A point system allows weight to be given to several different priorities and thus has proved useful for organ allocation. Moreover, since the availability of organs from cadaveric donors hinges upon the willingness of the entire society to contribute, a trustworthy, dependable system must be in place. The ethical basis for the system should be widely known among the donating public and should be defensible in public forums. Society must perceive fairness throughout the process and good outcomes for transplant recipients. Factors such as time waiting, medical urgency, utility, i.e. outcome as measured by patient and graft survival, histocompatibility match, preservation time, procurement cost and other factors associated with enhanced survival are important considerations. Should organs go to those who have waited the longest or those who are the sickest or those who would realize the greatest benefit? There is not universal agreement with regard to the proper weighting of these competing priorities. They are the subject of continual, heated debate even as OPO's and transplant centers must function within an established system. The current listing criteria and allocation policies for solid organ transplantation in the United States are available to the public and to professionals on line at <http://www.optn.org/policiesAndBylaws/policies.asp>.

Each of the current UNOS/OPTN policies has been subjected to extensive review by committees

of patients, physicians, ethicists and others followed by a period of public comment and finally by adoption by the OPTN Board of Directors and certification by the Government. However, the OPTN by-laws and policies are a work-in-progress rather than a finished document. The process of scientific discovery that underpins allocation policies is never completed. Moreover, public attitudes shift over time and recent advances in medical science oftentimes outstrip social institutions of law, ethics and government. OPTN policy on allocation is a journey, not a destination. The political action which created the scientific registry has led to research that now permits evidence-based creation of improved allocation policies. Recent examples include proposals for changing the allocation policies both for kidneys and for livers procured from deceased donors in the United States.

IMPROVING KIDNEY ALLOCATION

It has long been known that histocompatibility matching improves the outcome of kidney transplantation.³ In fact the first UNOS point systems gave up to 10 points for HLA match but only 5 points for medical urgency. Mismatches at the HLA-A, -B, and -DR loci in various combinations were assigned point values. The current scheme of allocation gives the greatest advantage to recipients who have no HLA mismatch with their donor. HLA-A is no longer used as a criterion because subsequent analyses have shown it to be of little import compared to the negative impact HLA-A matching may have on the equity of organ allocation for citizens of all races. Most re-

cently the utility of using both -B and -DR mismatches for allocating kidneys has been questioned.⁴ The equity consideration of fairness to all racial groups has been juxtaposed against the relative impact on utility, i.e. rate of graft loss, in the actual UNOS allocation scheme. At the same time that HLA matching improves graft survival after kidney transplantation, it decreases the number of non-caucasians who undergo transplantation because most of the kidneys donated in the United States come from caucasian donors. Whereas there is no significant increase in relative risk of graft failure with 1 or 2 mismatches at the HLA-B locus, there is a highly statistically significant ($p < 0.001$) increase in graft loss with either 1 or 2 mismatches at the HLA-DR locus (relative risk 1.15 for 1 mismatch and 1.26 for 2 mismatches). However, the racial disparity in organ allocation which currently favors whites by 33% would be reduced to 27% by the elimination of HLA-B matching. The United States kidney allocation policy could be changed to improve equity without significantly sacrificing utility if HLA-DR, but not HLA-B matching were used to select kidney recipients. Achieving that goal may increase the minority population's faith in and support of the national system of transplantation, a necessary step to improve cadaver donor organ donation from the minority community.

IMPROVING LIVER ALLOCATION

The allocation of livers has been one of the most controversial issues facing UNOS and KONOS. The development of a continuous disease severity scale for adults (Model for End Stage Liver Disease or MELD) and a scale for children (Pediatric End Stage Liver Disease or PELD) has, for the first time, allowed the prediction of survival, hence the ranking of medical urgency and the priority for cadaver donor livers based on objective, simple variables.⁵ Those variables have been modified and validated to create the most useful statistical model ever applied to date to a system of organ allocation. Moreover, the MELD model together with the waiting list and liver transplant outcomes data acquired since instituting the MELD algorithm can be used for continuous

quality improvement of the system. Liver transplant survival benefit is evident for all of those with a MELD score > 17 and is greatest for the sickest patients.⁶ Moreover, patients on the waiting list with a MELD score of 14 or less are more likely to survive one year if they do *not* receive a liver transplant.

REALIZING DONOR POTENTIAL

The brain-death law in the United States was established more than 20 years ago.⁷ In 1968 the Ad Hoc Committee of Harvard Medical School established a definition of irreversible coma. The driving force was not organ transplantation but rather the question of deciding when to stop artificial support of patients in the modern intensive care unit with cardiac, respiratory and hemodynamic support that allowed cardiopulmonary function to be maintained long after all cognitive and other brain functions of the individual were irrevocably lost. In 1977 a collaborative study established criteria that allowed diagnosis of a dead brain. By 1981 the President's Commission for the Study of Ethical Problems issued guidelines for the determination of death. The President's Commission stated that "when respiration and circulation have irreversibly ceased, there is no need to assess brain function directly. When cardiopulmonary functions are artificially maintained, neurological criteria must be used to assess whether brain functions have ceased irreversibly". The President's Commission outlined criteria for determination of neurological death as well as discussed complicating conditions and proposed a model statute intended for adoption in every jurisdiction in the United States. Beginning in 1981 and now in place for more than 15 years in all 50 states and the District of Columbia, the Uniform Determination of Death Act states that "an individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions or (2) irreversible cessation of all functions of the entire brain, including the entire brain-stem, is dead". Despite the long history of brain death declaration in the United States, many physicians, and innumerable patients and families do not yet understand or accept the concept. The relatively

Table 5. US Liver (LTP) and Kidney (KTP) Transplantation within the UNOS (United Network for Organ Sharing) System

Year	1996	1997	1998	1999	2000	2001	2002	2003
Liver								
CD - LTP	4,018	4,101	4,424	4,497	4,592	4,670	4,969	5,350
LD - LTP	62	86	92	251	395	518	361	321
Kidney								
CD - KTP	7,721	7,761	8,019	8,037	8,116	8,223	8,528	8,661
LD - KTP	3,665	3,919	4,415	4,707	5,473	6,021	6,237	6,462

new brain death law in Korea which has been in effect only since 2000 must be explained and clarified over and over to the medical profession and the population-at-large.

A new incentive system based on social benefits is more constructive than the reward of a kidney to the harvesting OPO. The entire society should benefit from organ procurement, and the entire society should support it. Even with the growth in living donor transplantation over the past 8 years (Table 5), in the United States most kidneys and the vast majority of livers for transplant still come from cadaver donors. Among all of the organs transplanted in the United States in the past 15 years under UNOS, 79% have come from deceased donors. The corresponding percentage of organ transplants from deceased donors in Korea is 14.2% for kidneys and 11.8% for livers. The ability of KONOS to meet the transplant needs of the Korean people will depend upon the willingness of families to donate the organs of their deceased loved ones and upon the willingness of the medical community to identify and care for deceased organ donors in every hospital where they may be found.

CONCLUSION

Realizing the promise and managing the success of organ transplantation requires the creation of unique institutions. An Organ Procurement and Transplant Network (OPTN) must be capable of increasing the supply of cadaver donor organs, of allocating those organs properly to recipients with due consideration for equity and utility, and of

using scientific data to improve the system for the good of society. The OPTN should answer to the public and should expect public support. From January 1, 1988 through May 31, 2004 the United States OPTN has acquired data on 317,833 transplants of which 252,075 are from deceased donors and 65,758 are from living donors. As the Korean OPTN database matures, it can become a tremendous source of new information which can guide evolution and improvement of transplantation in Korea.

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