

Current Policies and Practices

The transplant community is joined under a nationwide umbrella: the OPTN, administered, since its inception, under contract by UNOS. UNOS, located in Richmond, Virginia, is a private, not-for-profit, membership corporation qualified as a charitable organization under Section 501(c)(3) of the Internal Revenue Code. UNOS also administers the U.S. Scientific Registry on Organ Transplantation under contract with the Department of Health and Human Services (DHHS). The U.S. Scientific Registry tracks all solid organ transplants since October 1, 1987.

UNOS members include every transplant program, OPO, and tissue-typing laboratory in the United States. Policies governing the transplant community are developed by UNOS membership through a series of regional meetings, deliberations at the national committee level, and final approval by a 40-member board of directors comprised of medical professionals, transplant recipients, and donor family members. All patients accepted onto a member transplant hospital's waiting list are registered with the UNOS Organ Center, where a centralized computer network links all organ procurement organizations and transplant centers (see Box 2-1 for definitions). Through the UNOS Organ Center, organ donors are matched to waiting recipients 24 hours a day, 365 days a year. UNOS uses a formula for matching based on medical criteria for each type of organ. Patients awaiting livers receive additional consideration based on the amount of time they have been on the waiting list. Those on the list for longer of periods of time are situated higher on the list, Appendix C of this report contains the current UNOS Liver Allocation Policies.

As described in Chapter 1, there are currently 11 regions, comprised of 62 OPOs, with 891 organ-specific transplant programs (125 liver transplantation programs). This chapter summarizes the current policies and priorities related to organ procurement and transplantation. Since OPOs are a key component of the

system, the discussion focuses on their operation and the organ allocation process. Particular attention is paid to liver allocation.

ORGAN PROCUREMENT ORGANIZATIONS

OPOs are nonprofit, private entities that facilitate the acquisition and distribution of organs. There are 62 nationally, all with similar responsibilities. As noted in Chapter 1, OPO service areas vary widely in geographic size and demographic composition, as well as in the number of hospitals, transplant centers, and patients served (GAO, 1997).

BOX 2-1 Definitions

OPO. An organ procurement organization is an organization that is accepted as a member of UNOS and authorized by the Health Care Financing Administration (HCFA) to procure organs for transplantation. For each OPO, HCFA defines a geographic procurement territory within which the OPO concentrates its efforts.

Transplant Center. A hospital that is a member of UNOS in which transplants are performed. A transplant center may also be called a transplant hospital.

Transplant Program. A transplant center, or hospital, may have one or more transplant programs. Each program oversees transplantation of one or more organ types.

UNOS Patient Waiting List. The computerized list of patients waiting to be matched with specific donor organs in hopes of receiving transplants. Patients are registered on the UNOS waiting list by UNOS member transplant centers, programs, or OPOs.

UNOS Match System. The computerized algorithm used to prioritize patients waiting for organs. It identifies potential recipients whose size or ABO type is compatible with that of a donor and then ranks these potential recipients according to the ranking system approved by the UNOS board.

Host OPO. The host OPO is the one that, having identified a potential organ donor, assumes responsibility for donor management and organ allocation.

Local and Alternative Local Unit. In most cases, the local unit is the OPO. Alternative local units, such as subdivisions of the OPO that function as distinct areas for organ procurement and distribution, entire states, UNOS regions, or other appropriate units, are acceptable if they can be demonstrated to the satisfaction of the UNOS Board of Directors to fulfill UNOS principles and adhere to applicable laws and regulations.

SOURCE: UNOS, 1999.

OPOs work with the medical community and the public through professional education and public awareness efforts to encourage cooperation in and acceptance of organ donation. They provide all the services necessary in a geographical region for coordinating the identification of potential donors, requests for donation, and recovery and transport of organs.

Federal regulations (42 CFR Part 486, Subpart G) require OPOs to meet service area and other performance requirements. Service areas must be “of sufficient size to ensure maximum effectiveness of organ procurement and equitable organ allocation.” As of January 1, 1996, each OPO must meet at least one of the following service area requirements:

1. Include an entire state or official U.S. territory.
2. Procure organs from an average of at least 24 donors per calendar year in the 2 years before the year of redesignation, or request and receive an exception to this requirement.
3. If it operates exclusively in a noncontiguous U.S. state, territory, or commonwealth, achieve the rate of 50 percent of the national average of all OPOs for both kidneys procured and transplanted per million population.
4. If it is a new entity, demonstrate that it can procure organs from at least 50 potential donors per calendar year.

In addition, each OPO must have a board of directors or an advisory board with the authority to recommend policies on donating, procuring, and distributing organs. The board must have a transplant surgeon from each transplant center in the OPO’s service area and representation from hospital administrations, tissue banks, voluntary health associations, and either intensive care or emergency room personnel, the public, and physicians or personnel skilled in human histocompatibility and neurology (§371(b)(1)(G) of the Public Health Service Act 42 U.S.C. 273(b)(1)(G)).

Demographic characteristics of a service area influence organ procurement. For example, the rate of donation among African American families is typically lower than among white families (Eckhoff et al., 1998; GAO, 1997). Further, most potential organ donors share certain characteristics, including causes of death, the absence of certain diseases such as AIDS, and being within a certain age range. However, OPO service area populations can differ greatly in these characteristics. Thus, the ratio of potential organ donors to the total population in the service area may vary greatly for OPOs (see Chapter 4).

Some OPOs have sharing arrangements between or among themselves. Two or more OPOs can agree to share organs, interregionally or intraregionally. OPOs distribute organs pursuant to a sharing arrangement with the prior approval by the OPTN 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 the OPTN. With the exception of arrangements that are approved for a finite time period to test a stated hy-

prothesis with defined parameters under controlled conditions, OPOs participating in a sharing arrangement must have geographically contiguous service areas.

OPO Performance Standards

The Health Care Financing Administration (HCFA) administers Section 1138 of the Social Security Act (42 U.S.C. 1320b-8), under which the agency sets performance standards for OPOs. The act requires the Secretary of DHHS to designate one OPO per service area and requires OPOs to meet DHHS-specified standards and qualifications to receive payment from Medicare and Medicaid.

Without HCFA certification, an OPO cannot continue to operate. Section 371(b)(3)(B) of the Public Health Service Act (42 U.S.C. 273(b)(3)(B)) provides that an OPO should “conduct and participate in systematic efforts, including professional education, to acquire all usable organs from potential donors.” In addition, each OPO must meet HCFA performance standards in at least four of five categories to remain certified by HCFA and receive Medicare and Medicaid payment (45 CFR Part 486).

The performance standards include numerical goals in each of the five categories based on performance per million population in the OPO service area. The five categories include number of (1) organ donors; (2) kidneys recovered; (3) kidneys transplanted; (4) extrarenal organs (hearts, livers, pancreata, and lungs) recovered; and (5) extrarenal organs transplanted. HCFA assesses OPOs’ performance standards and qualifications every 4 years.

THE ORGAN ALLOCATION PROCESS

When organs are donated, a complex process begins that involves sequential matching efforts first within a local area and then outside. The procuring organization accesses a centralized computer operated by UNOS, enters information about the donor organs into the computer, runs the match program, and coordinates the procuring and transplanting surgical teams. The computer program generates a list of potential recipients ranked according to medical and other criteria (e.g., blood type, tissue type, size of the organ, medical urgency of the patient, as well as time already spent on the waiting list, and distance between donor and recipient.) This list then reflects current allocation policies. Each type of organ has a specific matching algorithm because of differences among organs in their cold ischemic times and the requirements for improving the compatibility between the donor and the recipient. For livers, the list has three sections: (1) all medically suitable “local” patients in rank order by medical urgency status; (2) all medically suitable patients outside the local area but within the area’s OPTN region in similar rank order; and (3) all medically suitable patients outside the region in rank order.

After obtaining the list of potential recipients, the transplant coordinator contacts the transplant surgeon caring for the top-ranked local patient to offer the organ. Laboratory tests designed to measure the compatibility between the donor organ and recipient are necessary for some transplants. A surgeon will not accept the organ if these tests show that the patient's immune system will reject it. Surgeons also turn away organs that they believe are less than optimal because of the age or health status of the donor (Hanto, 1999). Often, a "backup" patient is notified, because the organ may be declined by the transplant center, at least for the patient for whom it was initially accepted. If the organ is turned down, the OPO contacts the transplant surgeon caring for the next patient on the waiting list, and so on until a recipient is identified. Once the organ is accepted, transportation arrangements are made and surgery is scheduled.

Although potential transplant patients may select from among most transplant hospitals in the United States (subject to insurance coverage), under current OPTN policies the number of organs available to a hospital does not rise or fall as the number of patients on its waiting list increases or decreases. Rather, it is largely dependent on the number of donors in that hospital's OPO area. As a consequence of a "local-first" allocation policy, most organs leave the local OPO area only if there are no local patients who could use them.*

Once the appropriate donor information is provided, a transplant center is allowed 1 hour from the time of the organ offer in which to communicate its acceptance of the organ. After 1 hour, the offering entity may offer the organ to the transplant center for the patient listed next in priority by the UNOS Match System. After a transplant center indicates its initial acceptance of an organ, the transplant centers or OPOs involved must agree upon the time organ procurement will begin. If the procurement time cannot be agreed upon, the host OPO may withdraw the offer.

If an abdominal organ has been unsuccessfully offered to appropriate transplant centers for allocation to local patients (or unsuccessfully offered to transplant centers through an approved regional sharing arrangement), the UNOS Organ Center can be used to allocate the organ first regionally, and then nationally, based on a point system set forth in UNOS policies.

Listing Criteria, Patient Status

Because the current liver allocation policies give weight to waiting time, some people believe that some physicians list patients for transplants as early as possible, perhaps long before they are ready for transplant. For a variety of reasons some patients do not come to the attention of transplant professionals until later in the course of their illness. As a result, persons with a comparable medical need for a transplant may have substantially different waiting times.

*An exception is the policy of "no-mismatch" or "six-antigen match" kidneys, which are shared nationally.

Critics of the current system say that current liver allocation criteria fail to differentiate adequately among different degrees of medical urgency and express a desire for substantial improvements in the use of objective medical criteria for the classification of patients. In some cases, existing allocation criteria are based on situational factors, such as whether a person is hospitalized, which are neither medical criteria nor necessarily good proxies for an underlying medical condition or urgency (see Table 1-2). UNOS revised the listing criteria recently to address some of these issues, and some people argue that these changes, combined with advances in transplantation medicine and the OPTN's extensive investment in patient information systems, have resulted in substantial improvements in standardizing the medical urgency classifications of patients. Potential organ recipients may be placed on the waiting lists of more than one transplant center (UNOS, 1999). This UNOS policy was established in large part as a response to demands from the patient community. Each local listing will be added to the OPTN patient waiting list, so that the same patient may be on the OPTN waiting list multiple times. A patient may transfer his or her primary waiting time from one transplant center to another. Waiting time accrued by a patient for one type of organ may also be accrued for a second organ, if it is determined that the patient requires a multiple-organ transplant.

Changes in Liver Allocation Policies

In 1996, the OPTN board approved a new liver allocation policy. The policy gave higher priority to transplanting patients with acute hepatic failure and primary nonfunction over chronic patients. Advocates of this change believed that patients experiencing acute fulminant liver failure (and therefore with only a few days to live) have a high probability of survival and a low re-transplantation rate if transplanted quickly. In changing the policy, the OPTN Board believed that it would increase the total number of people nationwide benefiting from liver transplantation (Showstack et al., 1999).

Patients with chronic liver disease and their advocates asserted that their chance to receive a liver had been decreased significantly by the new policy. In addition, they asserted that there was no significant medical justification for favoring the "acute" group, arguing that the acute patients did not have a better posttransplant survival rate than chronic patients. They also criticized having all chronic patients being grouped together, rather than differentiating among chronic patients and their varying medical conditions. Opponents of the new policy requested the development of a system of classification based on objective and relevant medical criteria and for broader sharing of organs (DHHS, 1998b).

In June 1997, the UNOS Board of Directors voted to implement a new policy. The newer policy places very ill patients with chronic disease in a separate status subgroup and also assigns them a second priority (i.e., after acute patients). DHHS claims that this change reduces, but does not eliminate, the disad-

vantage that had been imposed on chronic patients in 1996. In 1998 further changes were made to improve consistency in listing (see Table 2-1).

Most recently, in June 1999, UNOS announced a revision to its liver allocation policy that aims to broaden access for the most urgent patients (UNOS, 1999). Under the revised policy, livers will be offered first to the most urgent category of patients (status 1) within the “local” area of the donor, usually defined as the designated service area of one of the 62 OPOs nationwide. If no match is found for a local status 1 patient, the liver would be offered to status 1 patients throughout the UNOS region where the donation occurred before being considered for any less urgent candidates (See Appendix C).

TABLE 2-1 UNOS Liver Status for Patients ≥ 18 Years of Age According to Disease Severity

Status 1	Fulminant liver failure with life expectancy < 7 days <ul style="list-style-type: none"> • Fulminant hepatic failure as traditionally defined • Primary graft nonfunction < 7 days of transplantation • Hepatic artery thrombosis < 7 days of transplantation • Acute decompensated Wilson’s disease
Status 2A	Hospitalized in Intensive Care Unit for chronic liver failure with life expectancy < 7 days, with a Child-Pugh score of ≥ 10 and one of the following: <ul style="list-style-type: none"> • Unresponsive active variceal hemorrhage • Hepatorenal syndrome • Refractory ascites or hepatic hydrothorax • Stage 3 or 4 hepatic encephalopathy
Status 2B	Requiring continuous medical care, with a Child-Pugh score of ≥ 10 , or a Child-Pugh score ≥ 7 and one of the following: <ul style="list-style-type: none"> • Unresponsive active variceal hemorrhage • Hepatorenal syndrome • Spontaneous bacterial peritonitis • Refractory ascites or hepatic hydrothorax
Status 3	Requiring continuous medical care, with a Child-Pugh score of ≥ 7 but not meeting criteria for Status 2B
Status 7	Temporarily inactive

SOURCE: Keefe, 1998; data obtained from UNOS website (<http://unos.org>) initially implemented July 1997, modified January 1998.

CRITICISMS OF THE CURRENT POLICIES

Partly as a result of the controversy surrounding the new UNOS liver allocation policies, some have questioned whether a private sector agency (i.e., the OPTN contractor) can or should set policy for a system that has such a profound effect on life-and-death decisions (DHHS, 1998b).

In comments provided on the Final Rule, a number of individuals and organizations argued that the approval of a flawed liver allocation policy in November 1996 and the failure to improve current policy in more fundamental ways illustrate systemic flaws in the current governance structure, specifically the structure of the UNOS Board of Directors. Some assert that the OPTN is dominated by hospitals (large and small) and transplant surgeons and physicians, and that the greater public interests—the altruistic motives of donors and their families and the health and survival of potential recipients—are not given adequate attention. Still others claim that hospitals, physicians, and payers can manipulate the current system of organ allocation and listing by excluding high-risk patients from the list, listing patients early to gain waiting time points, listing patients at more than one transplant hospital to increase the chance of getting an organ, and referring high-risk patients to other hospitals to avoid adverse performance outcomes.

Criticisms and concerns have also been raised about the role of the federal government in the oversight, and regulation of decision making with respect to organ procurement and transplantation.

CONCLUSIONS

The discrepancy between the number of donated organs and the need for organ transplants has called into question current policies and practices regarding allocation and distribution of organs, particularly livers. There is ongoing controversy about the uniformity of listing criteria, referral practices, donation rates, access, and the effects of these factors on waiting times. The committee concludes that although controversy may continue regarding many of these issues, the objectives of uniform minimal listing criteria, better data collection, and greater accountability on the part of the organ transplant system, seem reasonable and should be pursued with vigor.