New UNOS Rules: Historical Background and Implications for Transplantation Management

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The algorithm for the allocation of donor hearts used by the United Network for Organ Sharing (UNOS) was changed in January 1999. The new scheme alters the medical urgency criteria from a 2-tiered to a 3-tiered system. Blood type O and blood type B candidates are less disadvantaged and pediatric candidates are somewhat advantaged with regard to adolescent donors. The new allocation algorithm allows an individual with life-threatening ventricular arrhythmias to be listed in the highest urgency status. Increased regulation will occur with the establishment of a review for the highest urgency status and the establishment of regional review boards. J Heart Lung Transplant 1999;18:1065–1070.

Just over a decade ago, the contract for the national organ procurement and transplantation network (OPTN) was awarded to a private, non-profit corporation called the United Network for Organ Sharing (UNOS). The UNOS developed foundational bylaws and an organizational structure with a board of directors and many permanent standing committees.[1] Without broad-based input from the heart transplant community, an untested, point-based allocation scheme for the distribution of cardiac allografts was established. Not surprisingly, the heart allocation scheme mimicked the algorithm used for cadaveric renal allograft distribution. Among the categories for which one received points was a 7-tiered medical urgency category, adopted directly from the renal allocation scheme, and the degree of HLA matching between donor and recipient. Distribution was first within an organ procurement organization (OPO), then within a UNOS region, and finally within the United States. Within the OPO, UNOS region, and nation, the individual who received the cardiac allograft was the one with the most points, based on the many point-generating categories.

To their credit, UNOS recognized the need for broader-based input and assembled an ad hoc committee of heart surgeons and cardiologists to review UNOS plans. The UNOS learned from those assembled that processes involved in heart transplantation could not simply use renal transplantation templates. Those assembled learned for the first time that UNOS was entrusted with an important stewardship, UNOS needed help, UNOS was willing to be helped, and that UNOS was probably preferable to a federal bureaucracy. The ad hoc committee unanimously recommended three things, that the heart transplant committee be made a permanent standing committee, that a heart transplant professional be seated on the board of directors, and that the heart transplant committee be charged with developing a heart-appropriate allocation scheme. The UNOS board of directors approved all of the recommendations.[1]

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1053-2498/99/$–see front matter PII S1053-2498(99)00075-3

TABLE I Comparison of 1989 and new allocation algorithms for hearts

Component	1989–1999 System	New System
Medical urgency	2-tiered, Status 1 and Status 2	3-tiered, Status 1A, 1B, and 2
Geographic sequence	Local, Zone A, Zone B, and Zone C	Local, Zone A, Zone B, and Zone C
ABO Blood Type	Identical/compatible differentiated for Status 2 but not for Status 1	Type O to O or B (first), A to A or AB, B to B or AB
Time waiting	Status 1 time = Status 1 time; Status 2 time = Status 1 + Status 2 time	Status 1A time = Status 1A time; Status 1B time = Status 1A + 1B time; Status 2 time = Status 1A + 1B + 2 time
Heart–lung	Separate category, allocated after Status 1 heart	On both heart and lung lists; lungs go with heart or heart goes with lungs if no Status 1A heart
Pediatric issues	<6 months old may be Status 1	Separate urgency criteria, preference to pediatric recipient for adolescent donor
Sensitized patients	Local agreement	Local agreement
Regulatory issues	Status 1 random audits of ICU location	Regional review boards, Status 1 justification forms

Notably, UNOS has followed this pattern. When a geographically and professionally diverse heart transplant committee, or thoracic organ transplantation committee as it was later named, developed a consensus opinion or recommendation, UNOS has generally responded favorably. When UNOS has been criticized for issues relating to heart transplantation, it is usually because the heart transplant community has failed to deal with the issue or because of the failure to reach any semblance of consensus on the particular issue. For instance, UNOS would have had a much easier time establishing transplant surgeon, physician, and center qualifications if professional societies had tackled the issue before they, as required by the OPTN contract, had to deal with it. Motivated by self-interest, many have tried to politicize the process. For example, early on, UNOS received an application from a center where the submitted qualifications for the surgeon were that he had performed 3 transplants in pigs (survival data were not supplied). However, UNOS, with input from their membership and professional standards committee and the heart transplant committee, recommended disapproval. Within 24 hours of the center being notified of disapproval, one of the U.S. senior senators, at the request of the center, contacted UNOS and expressed, in the strongest terms, his dismay at how anyone in his state could be so discriminated against. Similarly, ongoing challenges that include the standardization of meaningful recipient selection criteria and cardiac allograft allocation meet occasionally with parochial, self-centered, and obstructionist tendencies. Unfortunately, then and now, many transplant centers and professionals want UNOS to simply be a strong force to govern (others) and to leave them alone, contrary to the spirit of the OPTN-legislated mandate.

ALLOCATION ALGORITHMS

A consensus allocation system was developed and remained in force from January 1989 until January 1999 (referred to hereafter as the 1989 system).[2] A comparison of the 1989 system and the new allocation algorithm is shown in Table 1.[3–5]

Medical Urgency

In the 1989 system, medical urgency was divided into only 2 categories. Status 1 was for individuals requiring a total artificial heart, left or right ventricular assist device, intra-aortic balloon pump, or ventilator. Further, a patient could be Status 1 if he or she was in an intensive care unit (ICU) and *required* inotropic therapy. The only pediatric consideration was that patients less than 6 months of age could also be listed as Status 1. Status 2 was for all others actively listed.

The 2-tiered, 1989 system can be criticized because it did not allow some critically ill patients, such as those with unstable, untreatable, life-threatening ventricular arrhythmias, to be in the highest urgency status. Pediatric needs were poorly accommodated. The algorithm was difficult to monitor and police, and was developed before the advent of the current generation ventricular assist devices (VADs). The 1989 system's Status 1 encompassed a wide range of acuity and some argued that the highest urgency status should include only those

TABLE II A New algorithm: medical urgency—adult

Status 1 A
- I. Patient admitted to listing transplant center hospital
- II. At least one of the following devices/therapies:
  1. Mechanical circulatory support (at least one)
     - A. Left and/or right ventricular assist device, ≤30 days
     - B. Total artificial heart
     - C. Intra-aortic balloon pump
     - D. Extra-corporeal membrane oxygenator
  2. Mechanical circulatory support >30 days but with device-related complications (e.g., thromboembolism, device infection, mechanical failure, or life-threatening ventricular arrhythmias)
  3. Mechanical ventilation
  4. High-dose intravenous inotrope (dobutamine ≥7.5 mcg/kg/min or milrinone > 0.5 mcg/kg/min), multiple inotropes, continuous hemodynamic monitoring (valid only for 7 days with onetime 7 day renewal for each Status 1A recurrence)
  5. Life expectancy <7 days, valid only for 7 days, recertification by attending physician every 7 days (Regional Review Board and Thoracic Organ Transplantation Committee review)
- III. Heart Status 1A Justification Form within 24 hours or listing or continuance

Status 1B

At least one of the following:
1. Left and/or right ventricular assist device >30 days without complication
2. Continuous infusion of intravenous inotropes

Status 2

All other actively listed patients

with the highest pre-transplant mortality risk. Interestingly, the data show that Status 1 survival after transplantation was not very different from that in Status 2 recipients, indicating that, in the 1989 system, allografts were not generally going to only patients with a poor prognosis after transplantation.

In an attempt to address these criticisms, the UNOS Thoracic Committee developed a new proposal, which was approved by the UNOS Board of Directors in March 1997. The proposal was sent to 5200 individuals and organizations for public comment. A public forum was held in September 1997. In February and May 1998, the allocation policy was further reviewed and modified based on public comments by the UNOS Thoracic Committee. The modified proposal was reapproved by the UNOS Board of Directors in June 1998, and was implemented, as mentioned, in January 1999.[3–5] In the new system, medical urgency is expanded to 3 tiers and is modified by age. The adult criteria pertain to those 18 years of age and older. The pediatric criteria pertain to those who are younger than 18.

In the new system, for adults and children to qualify for the various urgency levels, they must meet the criteria set out in Table 2. In the new system, a patient in the highest urgency status must be in the transplant hospital and a stronger regulatory component is implemented, with justification forms and the establishment of regional review boards. All mechanical circulatory support is not treated equally. The time constraint with VADs is notable. The rationale is that the mortality in the first 3 weeks after VAD placement is 5% to 10% per week. Though these patients are included because their pre-transplant mortality risk is high, these same patients may have the worst outcomes after transplantation if transplanted too soon. Also of note, a patient qualifies for Status 1B even if on home dobutamine, regardless of dose.

An additional twist in the new UNOS rules relates to the allocation of hearts from donors who are 11 to 17 years of age (adolescent donors). Within each status, geographic zone, and blood type, a heart retrieved from an adolescent donor will be allocated to a pediatric heart candidate, defined as being less than 18 years old, before the heart is allocated to an adult candidate. Given the well-known higher risk of developing allograft coronary artery disease with advancing donor age, the modification to advantage pediatric recipients is justified without further discussion. However, as presented to UNOS, the allocation modification was based of the data shown in Table 3.[6] Among Status 1 recipients who are 11 to 17 years old who receive a donor heart from an 11 to 17 years old, 1 month survival is 98%. In contrast, 11- to 17-year-old Status 1 recipients who receive a

TABLE II B New algorithm: medical urgency—pediatric

Status 1A
- I. At least one of the following devices/therapies
  1. Mechanical circulatory support
  2. Balloon pump
  3. Mechanical ventilation
  4. <6 months old, prostaglandin E, or pulmonary hypertension at >50% systemic pressures
  5. High-dose or multiple intravenous inotropes (dobutamine or dopamine ≥7.5 mcg/kg/min)
  6. Unresponsive, recurrent life-threatening arrhythmias (if all thoracic organ transplant centers within the OPO agree)
- II. Heart Status 1A Justification Form within 24 hours of listing

Status 1B
- At least one of the following:
  1. Low-dose intravenous inotropes (dobutamine or dopamine <7 mcg/kg/min)
  2. <6 months old, not meeting criteria as Status 1A
  3. Falls off growth curve and exhibits poor systemic ventricular function, or has failed previous surgical intervention

Status 2
- All other actively listed pediatric patients

OPO, organ procurement organization.

heart from a donor who is 18 or older, 1 month survival is 82%. Some have argued that if this were related to a fundamental, biological reason, a similar, differentially worse survival rate would also be seen in Status 2 recipients who are 11 to 17 years of age. However, 1-month survival in adolescent Status 2 recipients is 98% when a 11- to 17-year-old donor is used and 94% when the donor is 18 or older. Critics have argued that the finding likely relates more to the reasons why one would use an older heart in a younger Status 1 recipient. In other words, one would use a 50-year-old donor heart in a 15-year-old candidate only if the situation were dire. Regardless, giving an advantage to pediatric patients appears appropriate for other reasons, such as the fact that allograft coronary artery disease is increased with increasing donor age. This alone appears to be sufficient justification to allow this minor pediatric advantage.

The impact of the new urgency statuses is likely underestimated. In briefing papers, the UNOS board was told that a review of UNOS data on Status 1 patients suggested that fewer than 10% of patients would be redesignated as Status 1A.[3–5] However, an audit performed on January 27, 1998, reveals that of 355 candidates verified as being Status 1 patients, 90 would be reclassified as 1A and 265 would be reclassified as 1B. Thus, using UNOS's own data, fully 25% will be reclassified from Status 1 to Status 1A, not 10%. Furthermore, this audit does not take into account that more patients will be added to the 1B status from the current Status 2 category because no location restriction is imposed on the inotrope-use criteria for Status 1B.

Geographic Sequence

In the new algorithm, geographic distance from the donor hospital does not differ from the 1989 system. The UNOS regional boundaries play no role. Distribution occurs first locally, within the OPO or an approved alternative local unit (ALU). Once yielded from the OPO or ALU, a donor heart is allocated nationally in 3 zones defined by concentric circles of 500 and 1000 nautical miles, with the donor hospital at the center. Zone A extends to 500 miles. Zone B is between 500 and 1000 miles, and

TABLE III Donor age and adolescent survival

Urgency	Recipient Age (years)	Donor Age (years)	Survival 1 month	Survival 1 year
Status 1	11 to 17	11 to 17	98%	89%
Status 1	11 to 17	≥18	82%	76%
Status 2	11 to 17	11 to 17	98%	91%
Status 2	11 to 17	≥18	94%	88%

TABLE IV Geographic allocation sequence

1989–1999 Algorithm	Zone	New Algorithm
Status 1 patients	Local*	Status 1A patients
Heart–lung patients**	Local	Status 1B patients
Status 2 patients	Local	Status 2 patients
Status 1 patients	Zone A	Status 1A patients
Heart–lung patients	Zone A	Status 1B patients
Status 1 patients	Zone B	Status 1A patients
	Zone B	Status 1B patients
Heart–lung patients	Zones B & C	Status 1C patients
Status 2 patients	Zone A	Status 2 patients
Status 2 patients	Zone B	Status 2 patients
Status 1 patients	Zone C	Status 1A patients
	Zone C	Status 1B patients
Status 2 patients	Zone C	Status 2 patients

*Local, organ procurement organization or alternative local unit.
**In the new algorithm, heart–lung patients will not be considered a separate category per se (see text for clarification).

Zone C is beyond 1000 miles. The zones are established in this way to facilitate coordination and to decrease ischemic time.

Table 4 compares the geographic sequence in the 1989 and the new allocation algorithms. In both systems, the geographic sequence for heart distribution is, in essence, the same. In the 1989 system, if we ignore the heart–lung recipient and substitute for Status 1 first 1A followed by 1B, the algorithms can be seen to be the same. In the 1989 system, heart–lung recipients come after Status 1 heart recipients in any sequence step.

Heart–Lung Allocation

In the new system, heart–lung recipients will not be considered a separate category per se. A heart–lung recipient will be registered with UNOS on both the heart and lung waiting lists. When the patient is eligible to receive a heart, in accordance with the allocation policy for hearts, the lung will be allocated from the same donor. Alternatively, when the patient is eligible to receive a lung in accordance with the allocation policy for lungs, the heart will be allocated from the same donor if no suitable Status 1A isolated heart candidate is eligible to receive the heart. For instance, in any zone, a heart–lung candidate listed as Status 2 on the heart waiting list will never get the heart–lung block unless there is no Status 1A recipient eligible. However, if a candidate qualifies for the lungs from a donor based on the lung waiting list, the candidate will get the heart also, even if there are Status 1B heart candidates that are eligible.

TABLE V Median time to transplantation (days)

Year	Blood Type O	Blood Type A	Blood Type B	Blood Type AB
1988	165	89	108	69
1995	355	154	155	89
Increase	115%	73%	44%	29%

Blood Type

In the 1989 system, Status 1 patients who are blood type ABO identical with a donor do not receive priority over candidates who are ABO compatible. In status 2, however, within a specified geographic zone, ABO identical recipients receive the offer first, followed by ABO compatible recipients. As can be seen in Table 5, between 1988 and 1995, the median waiting time to transplant for blood type O patients has increased 115%, from 165 days to 355 days.[7] Lesser increases are seen in blood type A, B, and AB patients. To try to alleviate the longer waiting times for blood type O patients, which seems justified by the data, and to give an advantage to blood type B patients, which does not seem justified by these data, the new system modifies the allocation based on blood type. Within each heart status category and within each zone, a blood type O donor heart will first be allocated to blood type O or blood type B patients; a blood type A donor heart will be allocated to a blood type A or blood type AB patient; a blood type B donor heart will be allocated to blood type B or blood type AB patients; and blood type AB donor heart will, of course, be allocated only to AB patients. For example, in any zone, a blood type A candidate who is Status 1A will not receive the heart from a blood type O donor if there is a blood type O or type B Status 1A candidate available, even if the blood type A candidate has waited longer.

Waiting Time

In principle, waiting time is not altered in the new system and determines who gets the heart, all other characteristics being equal. Patients listed as Status 1A, 1B, or 2 will accrue waiting time within each heart status; however, waiting time accrued while listed at a lower status will not be counted toward heart allocation in a higher status. In other words, Status 1A waiting time is the time in that status.

Status 1B waiting time is the sum of 1A and 1B time. Status 2 waiting time is the sum of all waiting time, 1A, 1B, and 2.

Sensitized Patients

The modification that is allowed for the sensitized patient is unchanged in the new system. The allocation policies need not be used when all thoracic organ transplant centers within an OPO and the OPO agree to allocate to a sensitized patient because results of a donor-specific crossmatch are negative.

Regulation

The proposed algorithm introduces more regulatory issues with the creation of regional review boards and the requirement for a Status 1A Justification Form. Policing does make a difference. In the current system, initial random audits indicated poor compliance with Status 1 criteria. However, after routine auditing was widely known to be occurring, compliance improved. Unfortunately, the only measures that could easily be audited were whether or not the patient was in an ICU and whether or not a VAD was in place. In the new system, no specific auditing of patients listed as 1B has been proposed.

SUMMARY AND CRITIQUE

A summary of the changes is shown in Table 1. Medical urgency is 2-tiered in the 1989 system and 3-tiered in the new system. Geographic sequence is not different. Allocation is modified based on blood type to decrease waiting times for blood type O recipients and to advantage blood type B recipients. Time waiting is not different, with Status 1A time being just time in Status 1A. Status 1B time will include both 1A and 1B time. Status 2 time will include all active time. Heart–lung allocation will likely now follow heart allocation but is advantaged over 1B heart candidates if the patient qualifies from the lung waiting list. Pediatric issues have been more fully addressed. Sensitization issues continue to be dealt with locally. The new allocation algorithm allows an individual with life-threatening ventricular arrhythmias to be listed in the highest urgency status. The inability to do so was a serious deficiency in the 1989 system. However, this applies essentially only to patients in "electrical storm," satisfying the "life expectancy <7 days" criterion (Table 2). Increased regulation will occur. Increased supervision is warranted, simply because of the experience with Status 1 audits. Individual centers are less likely to "cheat" if they know they will or can be caught. There will be tighter control and scrutiny of the most severely ill, those classified as 1A. The requirement of the 1A patient to be in the transplant hospital seems most appropriate. Since no specific auditing of moderately ill patients, those listed as 1B, has been proposed, it is unknown what will happen. Given the fact that no stringent requirements or criteria are set for the use of inotropes and the obvious allocation advantage of 1B listing, a much bigger proportion of patients being classified as 1B will likely occur. Clearly, someone who *requires* inotropic therapy is at greater risk for mortality than someone who does not. To what extent this listing criteria will encourage the inappropriate use of inotropes remains to be seen but will be difficult to assess.

The development of pediatric-specific criteria and the adolescent donor allocation policy are improvements over the 1989 system. We do not know what impact the tacit encouragement of the early transplantation of VAD patients will have. Many of those in the first several weeks after VAD placement should not be transplanted until they have sufficiently stabilized. While the heart transplant community needs to support UNOS in this new allocation algorithm, it must carefully evaluate outcome data as they become available and push UNOS for prompt changes, if indicated. The ideal allocation system must be able to quickly respond to the rapidly evolving field lest all "current" allocation schema be outdated.

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