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Special Article

Lung and Heart Allocation in the United States

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Lung and heart allocation in the United States has evolved over the past 20–30 years to better serve transplant candidates and improve organ utilization. The current lung allocation policy, based on the Lung Allocation Score, attempts to take into account risk of death on the waiting list and chance of survival posttransplant. This policy is flexible and can be adjusted to improve the predictive ability of the score. Similarly, in response to the changing clinical phenotype of heart transplant candidates, heart allocation policies have evolved to a multitiered algorithm that attempts to prioritize organs to the most infirm, a designation that fluctuates with trends in therapy. The Organ Procurement and Transplantation Network and its committees have been responsive, as demonstrated by recent modifications to pediatric heart allocation and mechanical circulatory support policies and by ongoing efforts to ensure that heart allocation policies are equitable and current. Here we examine the development of US lung and heart allocation policy, evaluate the application of the current policy on clinical practice and explore future directions for lung and heart allocation.

Key words: Heart allograft, lung allograft, organ allocation, transplant waiting list, transplantation

Abbreviations: DSA, donation service area; ECMO, extracorporeal membrane oxygenation; HHS, Health and Human Services; HRSA, Health Resources and Services Administration; IABP, intraaortic balloon pump; ICU, intensive care unit; iPAH, idiopathic pulmonary arterial hypertension; IPF, idiopathic pulmonary fibrosis; LAS, lung allocation score; LVAD, left-ventricular assist device; MCS, mechanical circulatory support; NOTA, National Organ Transplant Act; OPO, organ procurement organization; OPTN, Organ Procurement and Transplantation Network; RRB, regional review board; RVAD, right-ventricular assist device; SRTR, Scientific Registry of Transplant Recipients; TAH, total artificial heart; UNOS, United Network for Organ Sharing; VAD, ventricular assist device.

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Introduction

The allocation of hearts and lungs for transplant in the United States involves distribution of a limited resource to a select few of the transplant candidates in need. The goals of lung allocation policies have evolved over the past three decades; the primary challenge now is to find methods that will allow equitable access to organs while maximizing the net benefit of transplant. Today, the Lung Allocation Score (LAS) is the primary determinant of candidate priority on the waiting list. Similarly, heart allocation has evolved over time. Since the first heart transplant was performed in 1967, the medical and surgical management of heart failure has changed dramatically, increasing survival among patients with heart failure and reducing morbidity and mortality among patients on the transplant waiting list. Concurrently, improved clinical management of heart transplant candidates has improved survival posttransplant. This overview does not discuss historical or current variances, but reviews the generally applied Organ Procurement and Transplantation Network (OPTN) national lung, then heart allocation policies.

Lung Allocation

History of lung allocation

The first lung transplant was performed by J.D. Hardy at the University of Mississippi in 1963; however, it would take 20 years before lung transplant was established as a treatment option for patients with end-stage pulmonary diseases (1). After the first transplant, refinement of the procedure proceeded slowly until the advent of cyclosporine in 1982; the emergence of this immunosuppressant

moved lung transplant beyond experimental medicine into mainstream therapy (2,3). After 1982, heart–lung and lung transplants were used to treat a growing number of pulmonary diseases and achieved substantially increased survival rates (4–6).

In 1984, Congress passed the National Organ Transplant Act (NOTA), which mandated creation of a national organ transplant organization to act as a registry and organ matching entity to monitor allocation across the United States. This Act led to creation of the OPTN to organize allocation policies and, later, the Scientific Registry of Transplant Recipients (SRTR) to monitor outcomes (7). The OPTN contract for day-to-day organ donation and waiting list management operations is carried by the United Network for Organ Sharing (UNOS) (8).

After the passage of NOTA, OPTN began tracking solid organ transplants, but lung transplants were included with the thoracic organs and were not separately monitored. In 1990, OPTN amended the thoracic organ policies to monitor lung allocation. Until 1995, lungs were allocated to candidates purely on the basis of time spent on the waiting list, blood type and geographic proximity of the donor to the candidate (9). Because mortality rates vary for different pulmonary conditions, the waiting-time-only allocation policy tacitly discriminated against candidates who were most likely to die while waiting for an organ. In 1995, to remedy this discrepancy, OPTN amended the allocation process to include a special dispensation for patients with idiopathic pulmonary fibrosis (IPF). This change gave candidates with IPF credit for an extra 90 days on the waiting list, in hopes that the extra time credit would expedite their access to organs. Despite this modification, overall waiting times continued to increase (10). Before long, more than half the candidates for transplant waited more than 2 years after listing to gain access to lungs. The dramatically increased waiting times meant that many candidates died while on the waiting list, and a disproportionate number of lungs were allocated to candidates with more stable diagnoses.

In 1999, 599 of the 4868 candidates on the waiting list died; this is a wait-list mortality rate of 190 deaths per 1000 patient-years at risk. The wait-list mortality rate was highest for diseases such as IPF (with a rate 70% higher than average at 323 deaths per 1000 patient-years) and lowest for diseases such as emphysema (114 deaths per 1000 patient-years at risk) (10). In part to address high wait-list mortality across all organs, the US Department of Health and Human Services (HHS) issued the Final Rule, effective March 16, 2000, to mandate development of organ allocation policies based on medical necessity rather than waiting time (11). As a result of this rule, OPTN created the Lung Allocation Subcommittee and charged it with developing an allocation process that would decrease the wait-list mortality rate and give access to organs to candidates most in need (12).

In 2005, OPTN approved the implementation of the LAS for lung allocation (13). The revised allocation policies removed the emphasis on waiting time and replaced it with a combination of geographic priority and the LAS, a calculation of illness severity and projected posttransplant survival that was intended to place the sickest candidates with the best chance of survival at the top of the waiting list. This was the first time "utility" of the transplant was included as part of an organ allocation policy (14; OPTN Policy 3.7.6.1). Adoption of the LAS decreased the size of the waiting list by reducing the incentive for early listing, and improved access to lungs for candidates at greatest risk of dying while on the waiting list.

The LAS-based allocation policy had a dramatic effect on lung transplantation trends in the United States. By 2006, the size of the waiting list had decreased from 2163 to 1031 candidates. The LAS also affected which candidates were gaining access to transplants. Patients with IPF underwent 23% of lung transplants performed each year before the LAS and more than 33% after the LAS (10). From its inception, the LAS was designed to be an evolving calculation, changing in response to altered cohort composition, improved therapies and identified gaps in the process.

Current lung allocation policies

In addition to the LAS, national lung allocation policy is based on geography, age and blood type (ABO) compatibility; other criteria, such as thoracic cavity size match, are considered at the local level. The LAS is calculated for all candidates aged 12 years or older. Geographic distribution remains a central consideration in organ allocation as a means of minimizing ischemic times. With a limited exception, lungs are first offered locally and then to candidates outside the local area, in defined zones extending from the donor hospital. Local is defined as within the organ procurement organization's (OPO) donation service area (DSA). OPTN/UNOS defines the zones as: A (within 0–500 miles, nonlocal), B (within 501–1000 miles), C (within 1001–1500 miles), D (within 1501–2500 miles) and E (>2500 miles) (14; OPTN Policy 3.7.2.). The predefined borders of DSAs may allow organs to initially be offered to candidates hundreds of miles from the transplant center, well beyond the extent of zone A. For example, lungs available in Minneapolis are first offered to candidates in the local DSA including Minnesota, North Dakota and South Dakota, but will not be offered to candidates across the Wisconsin border until zone A offers are made. This remains true despite the fact that a candidate in Wisconsin may be hundreds of miles closer to the organ than a candidate in western North Dakota (Figure 1).

Allocation of adult donor lungs

Lung allocation is first determined based on the age of the lung donor; adult donors are defined as aged 18 years or older. An organ from an adult donor is first offered to local wait-list candidates (Figure 2). Within the local area,

Figure 1: Lung transplant programs within each donor service area.

candidates aged 12 years and older have priority over children (aged 0–11 years), primarily because of thoracic size considerations. Of the local candidates aged 12 years or older, those who are ABO identical with the donor (Figure 2, bin 1) have priority over those who are nonidentical but ABO compatible (bin 2). The LAS is considered at this point, determining which of the local ABO identical candidates aged 12 years or older will be offered the lungs first. If none of those candidates accept the organ, it is offered to local ABO compatible candidates aged 12 years or older. If none of those candidates accept the organ, it is allocated to child candidates. Children are designated priority 1 or priority 2, based on severity of illness. Offers of adult lungs to children are made to priority 1 candidates first, then to priority 2 candidates. Offers are made to priority 1 local ABO identical children (bin 3), then to priority 1 local ABO compatible children (bin 4), priority 2 local ABO identical children (bin 5), and priority 2 local ABO compatible children (bin 6). If all offers within the local zone are turned down, the organ is offered in the same order to candidates in zone A, then sequentially to candidates in zones B, C, D and E. If the lungs are offered to a candidate who needs only one lung, the remaining lung is matched to another single-lung candidate (14; OPTN Policy 3.7.11).

Transplant centers are responsible for evaluating any determining factors not indicated or proscribed by the allocation policy. For example, considerations such as thoracic size, organ quality, and other factors are left up to the individual transplant center, surgeon and patient (14; OPTN Policy 3.7.1.1).

To ensure that LAS and illness severity are accurately assessed, lung transplant candidates must be up to date on all critical measures for predicting wait-list and posttransplant survival (Table 1). All noninvasive criteria are updated once in every 6-month interval following listing (14; OPTN Policies 3.7.6.3 and 3.7.6.3.2). If a measure that does not require clinical testing, such as functional status, is not updated during an interval, the candidate's LAS score reverts to zero until the measure is updated. Candidates with LAS of zero are screened from the organ matching process. Noninvasive clinical measures must also be updated during every 6-month interval or the measure will be replaced with the least beneficial value and the candidate's LAS will be recalculated using the substituted data. Ties between candidates are broken using accumulated active waiting time (14; OPTN Policy 3.7.9).

Allocation of adolescent donor lungs

Adolescent donors are defined as aged 12–17 years. Although the LAS is used to allocate organs to adolescent candidates much like adults, adolescent organs are

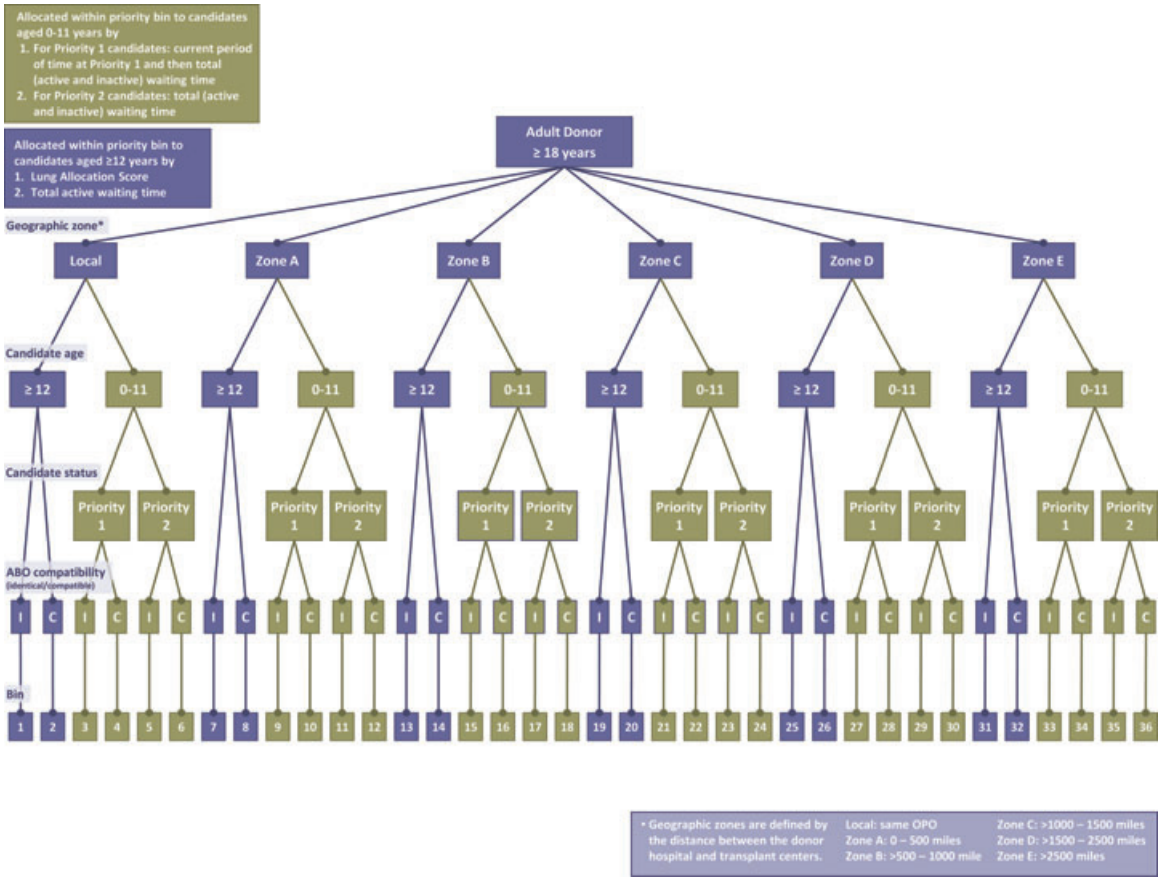

Figure 2: Allocation of adult donor lungs. This figure can be downloaded in color from www.srtr.org.

Table 1: Measures used to calculate the lung allocation score

Factors used to predict waiting list survival
Forced vital capacity (FVC)
Pulmonary artery systolic pressure (PA) for groups A, C and D[1]
O_2 required at rest for groups A, C and D
Age
Body mass index (BMI)
Diabetes
Functional status
6-min walk distance
Continuous mechanical ventilation
Diagnosis
PCO_2
Factors used to predict posttransplant survival
Forced vital capacity (FVC) for groups B and D
Pulmonary capillary wedge (PCW) pressure $\geq$ 20 for group D
Continuous mechanical ventilation
Age
Serum creatinine
Functional status
Diagnosis

[1] Group A, obstructive lung disease; Group B, pulmonary vascular disease; Group C, cystic fibrosis and immunodeficiency disorders; Group D, restrictive lung disease.

preferentially offered to adolescent candidates (Figure 3). When adolescent lungs become available, they are first offered to local candidates. The offer is first made to local ABO identical adolescent candidates, then to local ABO compatible adolescent candidates. If there are no suitable adolescent candidates in the local DSA, local child candidates are next in line. The lungs are offered to local adult candidates only if they have been turned down by all adolescent and child candidates in the local area. After the local candidate population has been exhausted, the lungs are offered in the same order to candidates in zones A, B, C, D and E (14; OPTN Policy 3.7.11.1).

Allocation of child donor lungs

For allocation purposes, child donors are defined as children aged 0–11 years. When the LAS-based allocation policy was implemented in 2005, children were excluded from the policy due to differences in diagnoses that made the LAS calculation inappropriate as a measure of medical urgency. Child candidates are ranked as priority 1 if they fulfill certain set criteria, or as priority 2 (Table 2; 14; OPTN Policy 3.7.6.2). Candidates who do not meet priority 1 criteria and are not inactive are designated priority 2. Qualified priority 1 candidates within a specific geographic zone are always

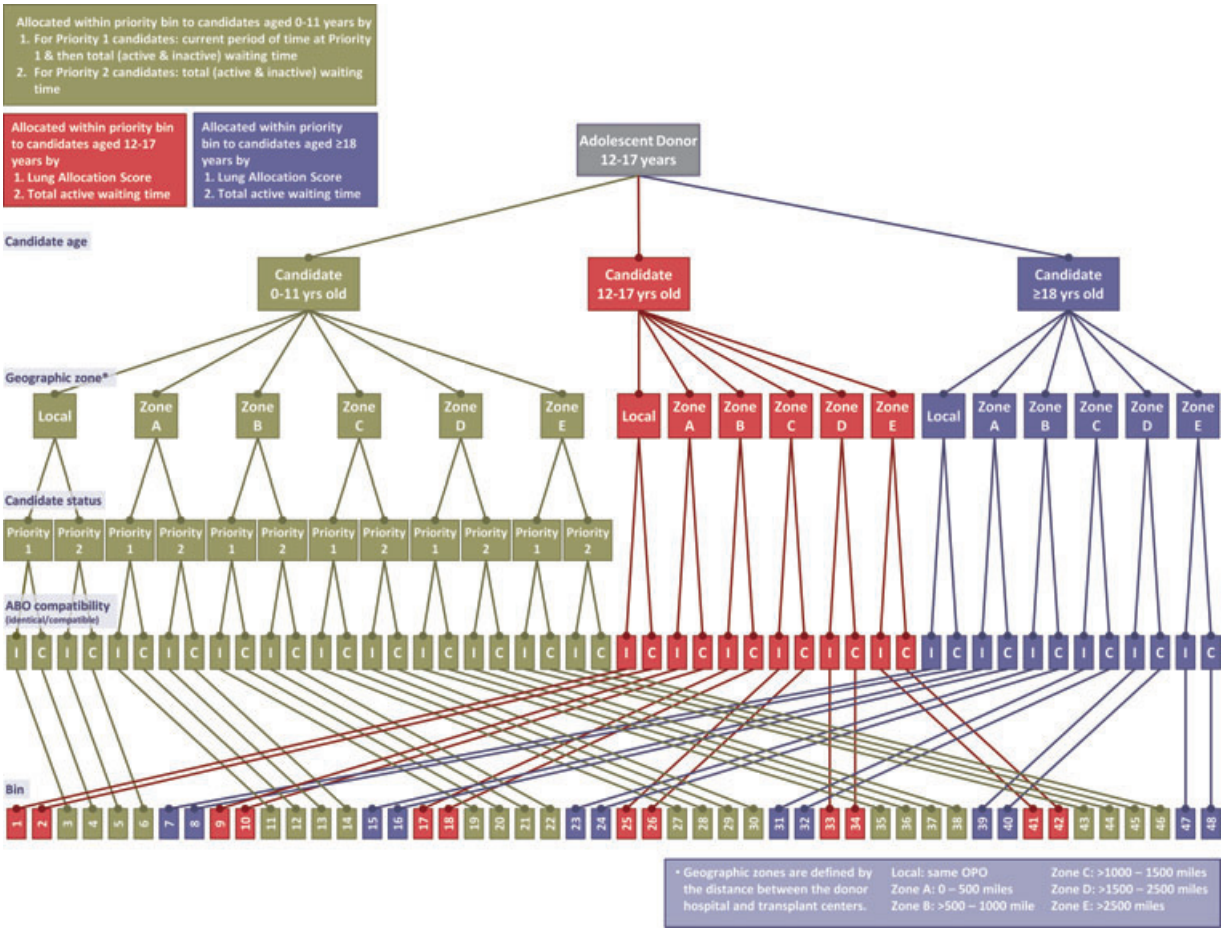

Figure 3: Allocation of adolescent donor lungs. This figure can be downloaded in color from www.srtr.org.

Table 2: Criteria for determining Priority 1 child candidates

Candidates must have one or more of the following:
Respiratory failure
Requiring continuous mechanical ventilation; OR
Requiring supplemental oxygen delivered by any means to achieve $FiO_2 > 50\%$ to maintain oxygen saturation levels > 90%; OR
Having an arterial or capillary $PCO_2 > 50$ mmHg or a venous $PCO_2 > 56$ mmHg
Pulmonary hypertension
Pulmonary vein stenosis involving three or more vessels; OR
Exhibiting any of the following, in spite of medical therapy:
Suprasystemic pulmonary artery pressure on cardiac catheterization or by echocardiogram estimate
Cardiac index < 2 L/min/m^2
Syncope or hemoptysis

ranked above priority 2 candidates. Within the priority rankings, candidates are ordered by ABO compatibility, then by waiting time. Waiting time for priority 1 candidates is defined as the time spent waiting as a priority 1 candidate since the most recent listing at priority 1. Priority 1 candidates cannot sum the total of all time spent waiting if they have multiple priority 1 periods. Total waiting time, defined as the sum of priority 1, priority 2 and inactive time, is used to break ties between priority 1 candidates (14; OPTN Policy 3.7.9.3). Priority 2 candidates are ranked by total waiting time. As always, the transplant center considers thoracic size, organ quality and other indicators when deciding if the organ is appropriate for transplant.

Just as with adult candidates, clinical data must be updated at least once in every 6-month interval (14; OPTN Policies 3.7.6.2 and 3.7.6.3). Failure to keep clinical data up to date will reduce a candidate's status from priority 1 to priority 2. Candidates remain at priority 2 as long as they are in need of an organ, unless they are removed from the list by the transplant center. The process of child donor lung allocation is illustrated in Figure 4.

When lungs become available from a child donor, they are preferentially offered to child candidates (ages 0–11 years). Due to the difficulty in finding a size match, this priority is

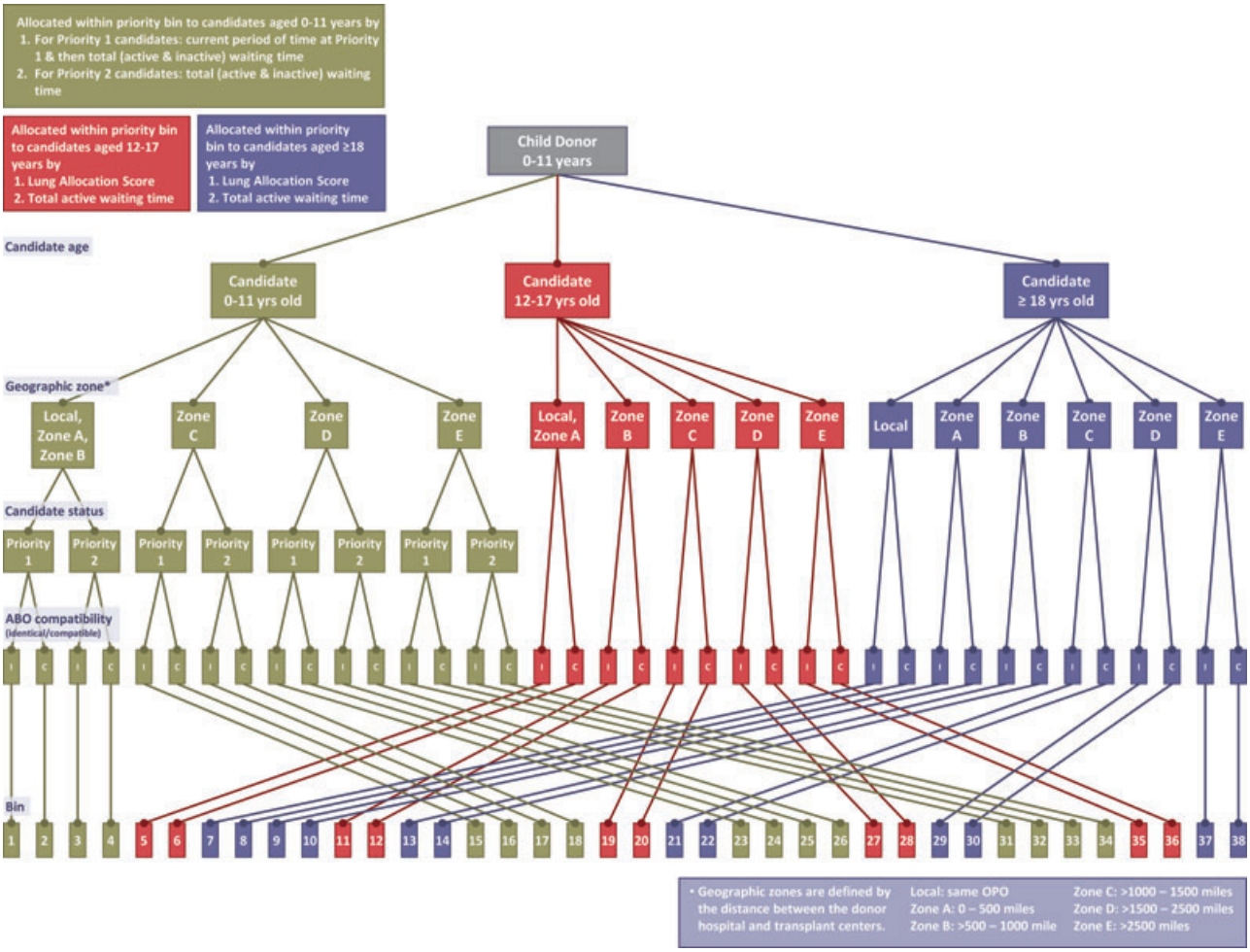

Figure 4: Allocation of child donor lungs. This figure can be downloaded in color from www.srtr.org.

critical to children on the waiting list. First, offers are made to child candidates from the local DSA, zone A, and zone B combined. Within that expanded geographic area, the first offer is made to a priority 1 ABO identical candidate (Figure 4, bin 1). If that offer is declined or there is no suitable candidate at that level, the next offer is made to a priority 1 ABO compatible candidate from the local area, zone A, or zone B (bin 2). Priority 2 candidates are offered the lungs if there are no suitable priority 1 candidates (bins 3 and 4). Successive offers are made to the following candidates in order: adolescent ABO identical candidates from the local area and zone A combined (bin 5), adolescent ABO compatible candidates from the local area and zone A (bin 6), adult ABO identical candidates from the local area (bin 7), adult ABO compatible candidates from the local area (bin 8), adult ABO identical candidates from zone A (bin 9) and adult ABO compatible candidates from zone A (bin 10). If there are no suitable candidates, the lungs are offered to adolescents in zone B (bins 11 and 12) and adults in zone B (bins 13 and 14) before being offered to child candidates in zone C (bins 15–18). If there are no acceptable child candidates in zone C, the organs will be offered to adolescents in zone C (bins 19 and 20), then to adults in zone C (bins 21 and 22). If no suitable candidates are identified, the order of offers in zone C is followed for zones D and E (bins 23–38) (14; OPTN Policy 3.7.11.1).

Allocation exceptions

The current allocation policy allows for special review of exceptional cases when the treating transplant team believes that the assigned LAS or priority level does not appropriately reflect the severity of the case, or when essential clinical values must be estimated to assign a score (14; OPTN Policy 3.7.6.4). Requests for exceptions to the standard scoring criteria are sent to the Lung Review Board through OPTN/UNOS. The Lung Review Board, a seven-member board selected from separate lung transplant centers, reviews all exception requests nationwide (15). The Board has 7 days to reach a decision about each case. If the exception is granted, the requested score or value applies for 6 months. If the candidate remains on the waiting list

6 months after being granted an exception, the request for exception must be renewed or the candidate's score will be recalculated according to the standard formulae (14; OPTN Policies 3.7.6.4, 3.7.6.1 and 3.7.6.3).

If the Lung Review Board denies the request for exception, the transplant center may appeal the decision. If the request is denied a second time, the transplant center has the option of overriding the decision of the Board. If the transplant center chooses to override the decision, the action will be reviewed by the OPTN/UNOS Thoracic Organ Transplantation Committee to determine if the center abused the override provision. If abuse is determined, the action may be referred to the Membership and Professional Standards Committee of OPTN/UNOS for evaluation (14; OPTN Policy 3.7.6.4).

The evolution of the LAS and future directions

The current LAS calculation was designed to be re-evaluated and refined as frequently as every 6 months. The first change to the LAS formula occurred in late 2008, when PCO_2 level was added to the LAS calculation (14,16; OPTN Policy 3.7.6.1 (b)). This parameter was added after analysis indicated that including PCO_2 values would increase the accuracy of the LAS in predicting wait-list mortality and posttransplant survival.

In 2008, OPTN approved the addition of bilirubin to the LAS calculation, although determining how bilirubin could be most effectively integrated into the calculation has taken some time (14,17; OPTN Policy 3.7.6.1 (c)). The proposed methodology for including bilirubin is expected to be factored in to LAS calculations sometime in 2012–2013. Although the bilirubin modification to the LAS will have little effect on most current transplant candidates, it will make a substantial difference for some candidates with idiopathic pulmonary arterial hypertension (iPAH), whose scores currently understate risk of death while on the waiting list.

The Lung Subcommittee of the OPTN/UNOS Thoracic Committee is in the process of developing and approving a revision to the LAS to improve the score's overall ability to predict wait-list mortality and posttransplant survival. This modification will include the already approved and developed bilirubin addition, and more comprehensive adjustments to the formula (18). The approval process to implement the fully revised LAS model has not been completed and the full effects of the final adjustments are not known. Modifications to the LAS calculation will continue as additional measures and criteria are determined to be predictors of waiting list and posttransplant outcomes. The required reviews of the formula have imparted flexibility that will allow the calculation to change with new criteria and changing candidate populations. Though the LAS assigned to an individual candidate may change based on evolving models, the mandate to decrease wait-list mortality and increase posttransplant survival will ensure that the candidates most in need will continue be prioritized on the waiting list.

Heart Allocation

History of heart allocation

We provide an overview of heart allocation policy evolution (Table 3) in response to changing trends in treatment and outcomes (including use of mechanical circulatory support [MCS] to stabilize critically ill patients awaiting transplant), historically, at present, and into the future. In the 1980s, OPTN assembled a policy review committee of heart surgeons and cardiologists, which became the Heart Transplant Committee. The Heart Transplant Committee expanded to include all thoracic organs in 1988, and in 1991 it became known as the Thoracic Organ Transplantation Committee. This committee primarily develops and monitors heart and lung organ allocation policies and reviews issues related to procurement and transplant, including the scientific, medical and ethical aspects. The committee is composed of regional representatives including physicians, surgeons or transplant coordinators; transplant hospital and OPO representatives; and at least one public or patient representative (e.g. a transplant candidate or recipient or a family member). Additional monitoring oversight is provided by the regional review boards (RRBs), which evaluate regional requests to list candidates as Status 1A or 1B by exception. Generally composed of transplant surgeons, physicians and coordinators, RRBs evaluate the appropriateness of exceptions on the basis of clinical information and compliance with OPTN policies.

To initially list a heart transplant candidate as Status 1A or 1B or to extend Status 1A time, the transplant center must submit a heart Status 1A or 1B justification form. OPTN is responsible for "the development, monitoring, enforcement and modification of the policies that govern the allocation, procurement and the transportation of deceased organs" (19). Policies under OPTN jurisdiction are outlined in detail in the Code of Federal Regulations (Final Rule) Part 42, section 121.4, and in the OPTN bylaws (20). Policy development is a collaborative process between OPTN, the transplant community, and the public. Any interested party may forward proposals for policies directly to the Committee Chair or via other representatives. Although time-limited variances may be established for experimental policies that test methods of improving allocation, most policy changes undergo lengthy evaluation and comment before implementation (20). When heart allocation policy changes are required or requested, the Thoracic Committee develops a proposal using data provided by UNOS and/or SRTR. Performance indicators and additional analyses may also be requested to measure the effect of the proposed changes. Required analyses may include the effect on various transplant programs due to transplant volume, risk-adjusted total life-years pre- and posttransplant, risk-adjusted waiting time and OPO performance. If the

Table 3: Summary of major changes to heart allocation policy

Date	Policy change
1988	Approved primary allocation criteria for hearts: medical urgency status; waiting time; distance of donor to recipient hospital and identical blood groups unless medical urgency dictated otherwise.
	Approved 2 medical urgency categories: Status 1 (candidates implanted with MCS device or admitted to ICU and requiring inotropic support) and Status 2 (all other candidates).
	Approved geographic zones A, B and C, comprising concentric circles with the donor hospital at the center (zone A, within 500 miles of the donor hospital; zone B within 1000 miles; zone C beyond 1000 miles).
	Permitted local OPOs to allocate hearts to potential recipients at local transplant programs on the basis of the primary allocation criteria.
	Permitted the Heart Transplant Committee, Organ Procurement and Distribution Committee, and Board of Directors to resolve local-level inequities or conflicts regarding donor heart distribution arising from prevailing OPO boundaries or policies.
	Established essential and desirable data needed for each heart offer.
1989	Required OPOs to apply to the Heart Transplant Committee to establish a variance.
	Prohibited inter-OPO sharing of hearts.
	Included allocation of lungs in the existing heart allocation criteria.
	Prohibited heart or heart–lung candidates from accruing waiting time while inactive on the waiting list.
1990	Enabled candidates aged $<$ 6 months to be categorized Status I.
	Changed "heart" to "thoracic organ" in the policy dictating the minimum data requirements for thoracic organ offers.
	Removed requirement to confirm blood typing of thoracic organs in the policy dictating the minimum data requirements for thoracic organ offers because rerunning the test is redundant.
1991	Required that heart and lung be recovered from a deceased donor if these organs could be transplanted.
	Made the host OPO responsible for appropriate donor management to assure recovery of multiple thoracic organs when possible.
1992	Permitted registration of *in utero* candidates on the waiting list.
1993	Permitted candidates to receive the waiting time accrued for 1 thoracic organ when listed for a second thoracic organ.
	Permitted a candidate to transfer waiting time for multiple thoracic organ transplant to a single thoracic organ.
	Required transplant programs to list candidates needing heart and liver transplants as two separate waiting list registrations.
	Created a joint heart–liver allocation policy that: (1) required the OPO to offer a heart and liver from a deceased donor to a joint heart–liver candidate if the donor and candidate were in the same local area and (2) recommended that OPOs voluntarily share the second required organ (heart or liver) if the candidate and the deceased donor were not in the same local area.
	Restricted accrual of Status 1 time to the period when the candidate was listed as Status 1.
	Allowed a candidate to carry over time accrued at Status 1 to Status 2.
1994	Required reporting of hepatitis B and C data for all thoracic organs offered.
	Stratified heart–lung match runs by acceptable donor height instead of donor weight.
	Required reporting of echocardiogram data, if the donor hospital has the facility to perform it, for all thoracic organs offered.
	Required all thoracic organ transplant centers within an OPO and the OPO to agree to prioritize a sensitized thoracic candidate for an organ offer.
1999	Prioritized pediatric candidates for receiving adolescent deceased donor heart offers.
	Prohibited use of an adult or pediatric candidate's level of sensitization as a reason for listing that candidate as Status 1A by exception.
	Permitted an adult or pediatric candidate's transplant center to determine the candidate's sensitization level.
	Implemented heart medical urgency Statuses 1A, 1B and 2 for adult and pediatric candidates.
	Assigned Status 1A to candidates with uncomplicated VADs for $\leq$ 30 days and admitted to the listing transplant center.
	Assigned Status 1A to candidates with complicated MCS for $>$ 30 days.
	Required submission of a heart Status 1A justification form to the OPTN contractor within 24 h of listing or recertification as Status 1A.
	Created the primary blood group matching system still in use.
	Allocated deceased donor hearts to local Status 1A, 1B and 2 candidates before offering them to Status 1A and 1B candidates in zones A and B (Status 2 candidates in zones A and B received deceased donor heart offers after Status 1A and 1B candidates in zones A and B).
	Dissolved variances that existed until this time, but participants in the dissolved variances could reapply in cases of need for alternative local allocation systems.
	Allowed adult and pediatric candidates to be listed as Status 1B by exception.
	Enabled adult and pediatric candidates in need of both a heart and lung to appear on lung match runs.
	Allowed for allocation of domino donor hearts.
2000	Required that RRBs approve extensions of Status 1A by exception listings, beyond an extra 7 days for adult and an extra 14 days for pediatric candidates.

Continued

Table 3: Continued

Date	Policy change
2001	Allowed submission of heart status justification forms via UNet.
	Lowered status to 1B automatically upon conclusion of a candidate's permitted time at a Status 1A criterion, unless the candidate's physician recertified Status 1A listing.
2002	Allowed candidates implanted with VADs to receive 30 days of time at Status 1A, regardless of admission to the listing center.
	Classified as blood type "Z" candidates listed *in utero* or able to accept an ABO-incompatible deceased donor heart offer.
	Allowed candidates aged < 1 year to receive ABO-incompatible deceased donor heart offers but only after these hearts were offered to ABO-compatible candidates.
	Allowed candidates *in utero* to receive deceased donor hearts after all born candidates.
2003	Created the geographic zone D for thoracic organ allocation.
2005	Removed inpatient requirement for adult candidates listed as Status 1A by criterion (b).
2006	Modified the heart allocation sequence so adult local and zone A Status 1A and 1B candidates receive heart offers from deceased donors aged 0–11 years and adult deceased donors before local Status 2 candidates; zone B Status 1A and 1B candidates receive these heart offers before zone A and B Status 2 candidates.
	Dissolved all programmed heart variances.
2007	Defined zone D as the geographic area 1500–2500 miles, inclusive, from the donor hospital.
	Created the geographic zone E, > 2500 miles from the donor hospital.
2009	Prioritized pediatric candidates to receive pediatric (ages 0–17 years, inclusive) deceased donor hearts.
	Combined local and zone A geographical areas for broader geographic sharing of pediatric donor hearts.
2010	Increased the maximum age for listing pediatric candidates for ABO-incompatible hearts from 1 to 2 years.
	Required isohemagglutinin titer data entry for all born candidates eligible to receive an ABO-incompatible heart offer, and set isohemagglutinin titer and treatment-based eligibility restrictions for ABO-incompatible transplants.
	Created an interim policy for adult, outpatient candidates implanted with TAHs allowing these candidates to be listed as Status 1A for 30 days.
2011	Required OPOs to provide human leukocyte typing of thoracic organs offered if requested to do so by the transplant programs receiving the organs offered.
	Codified the process whereby RRBs examine and approve requests to list candidates as Status 1A for device-related infection or complications not detailed in policy.
	Dissolved the Status 1 listing verification policy, as it was no longer current.
	Extended for 1 year the interim policy for outpatient candidates implanted with TAHs.
	Removed identification of specific inotropic agents from the adult heart policy, because the OPTN contractor maintains an updated list of these medicines in UNet.

ICU = intensive care unit; MCS = mechanical circulatory support; OPO = organ procurement organization; OPTN = Organ Procurement and Transplantation Network; RRB = Regional Review Board; TAH = total artificial heart; VAD = ventricular assist device.

proposal involves a substantive change in policy, the Committee distributes the proposal for public comment for a maximum of 45 days. Policy proposals that require immediate action due to patient health and safety concerns, that clarify or correct existing policy rather than substantively change it, or are administrative in nature do not require public comment (19). When the public comment period ends, the Committee submits a briefing document, including its responses to public comments and its final recommendations, to the Board of Directors, which then votes on the policy. Policies approved by the Board and recommended for enforcement as mandatory are forwarded to the Secretary of HHS for review and comment a minimum of 60 days before implementation, in accordance with OPTN Final Rule Section 121.4(b) (19). Mandatory policies cannot be enforced without the Secretary's approval. The Secretary may solicit guidance from the Advisory Committee on Organ Transplantation and elect to publish proposed policies in the Federal Register for public comment before approval (20). OPTN provides the Secretary and the membership with copies of its policies as they are adopted and publishes current and pending policies on the Internet for public access. OPTN heart allocation policies are re-evaluated periodically by the Thoracic Committee to determine whether they achieve their stated objectives and remain relevant in light of scientific and technological advances (19).

The overarching goal of heart allocation policy is to prioritize organ allocation to the most critically ill heart transplant candidates, as evidenced by the current urgency-based algorithm and ongoing policy deliberations. Over the past two decades, as the clinical profile of end-stage heart failure patients has evolved, heart allocation policies have similarly evolved. The original heart allocation system approved in 1988 was a two-tiered policy using medical urgency codes that applied to adult and pediatric candidates. Regional variances were allowed but required approval by the Heart Transplant Committee (Report of the Heart Transplant Committee to the Board of Directors, February 28, 1989). Hearts were allocated based on medical urgency code and time, first within the DSA, then within the OPO region and subsequently to the rest of the United States (20).

In 1989, the Heart Transplant Committee implemented the new allocation algorithm using only two tiers for medical urgency, Status 1 and Status 2. This policy, in effect until 1999, applied to adult and to pediatric candidates. Status I defined patients who required MCS, including total artificial heart (TAH), ventricular assist device (VAD), intraaortic balloon pump (IABP) or ventilator support; candidates in an intensive care unit (ICU) and requiring inotropes; and, in the one pediatric-specific consideration, candidates aged <6 months. All other actively listed heart transplant candidates were designated Status 2. Although this policy was an improvement over the prior system, it did not include in the highest urgency category other critically ill adult patients, such as those with untreatable, life-threatening arrhythmias or those in whom MCS or inotropes were contraindicated (20).

In 1999, OPTN implemented a major policy change that assigned higher priority to sicker Status I patients whose short-term survival was compromised. Medical urgency was expanded to three tiers (Status 1A, 1B, and 2). The highest urgency category (1A) required that candidates be admitted to the transplant center. Candidates whose life expectancy was <7 days could be listed and recertified as Status 1A after review by the RRB and Thoracic Organ Transplantation Committee. Candidates with VADs (and no VAD complications) for more than 30 days and candidates on continuous inotropes qualified for Status 1B. This new allocation scheme decreased median waiting times for Status 1A and 1B patients compared with prepolicy Status I patients, and decreased wait-list mortality (21).

The 1999 heart allocation policy change also established criteria for pediatric candidates (aged 0–17 years at the time of listing) and mandated that within each status category, adolescent donor hearts (ages 11–17 years) would be offered preferentially to pediatric candidates in an effort to improve wait-list survival (14,20,22). The preferential allocation to pediatric candidates resulted in more adolescent donor hearts being transplanted into pediatric recipients (23). Young donor hearts (ages 0–10 years), however, continued to be allocated according to the algorithm for adult donor hearts. As part of the broader geographic sharing initiative, the pediatric policy was revised in 2008 and implemented in 2009. This revision preferentially allocated *all* pediatric donor hearts (ages 0–17 years) to pediatric candidates and used the pediatric distribution sequence for all pediatric donor hearts rather than the adult distribution scheme for younger hearts as in the previous policy.

Monitoring oversight of Status 1A listings increased with the establishment of RRBs in 1999 and the requirement that Status 1A justification forms be completed by the transplanting center to justify a candidate's listing as 1A, which replaced random ICU audits under the previous policy. Increased oversight improved compliance with Status 1A listing policies (23). Table 4 lists the major adult and pediatric heart allocation policy changes, 1988 through 2011.

Adult candidates implanted with VADs

Early MCS devices improved survival over medical therapy, but were associated with significant device- and procedure-related complications and lacked durability (24). Newer devices have substantially fewer complications and improved durability compared with their predecessors. Heart allocation policies have kept pace with changes in VAD development and have been adjusted accordingly.

Under the 1989 policies, transplant candidates with VADs were categorized as Status I due to lack of durability of the devices and high complication rates. Beginning in 1999, candidates with VADs could be listed as Status 1A only if the device had been implanted for ≤30 days or for >30 days if a device-related complication occurred, such as thromboembolism, infection or mechanical failure. Candidates with TAH, IABP, extracorporeal membrane oxygenator (ECMO), mechanical ventilation or high dose inotropes also qualified for Status 1A. To minimize VAD-associated complications, candidates with left and/or right VADs (LVAD/RVAD) were upgraded to Status 1A for 30 days immediately after implantation regardless of medical stability or appropriateness for a second surgery.

In June 2002, OPTN discontinued the policy requiring Status 1A time to be accrued immediately after VAD implantation. As a result, candidates with VADs can be listed as Status 1A for 30 days any time after VAD implantation. The 2002 policy did not require that VAD patients be hospitalized to be listed as Status 1A, allowing VAD patients to stabilize before listing to minimize perioperative and post-transplant complications.

Pediatric candidates implanted with VADs

The 1999 changes to the pediatric heart allocation policy allowed pediatric candidates implanted with VADs or other MCS devices, including ECMO, to qualify for listing as Status 1A. Admission to the listing transplant center was not and is not required. No major policy change has occurred in this category since 1999.

Geographic sequence for organ distribution

Under early policies, heart allocation first occurred locally within the DSA or an approved alternative local unit. DSAs are geographic units served by an OPO. If no local recipient was identified, the donor heart was allocated to one of three zones defined by concentric circles of 500 nautical miles with the donor hospital at the center; zone A is within 500 miles of the donor hospital, zone B > 500–1000 miles, and zone C > 1000 miles. The zones were established to facilitate coordination and to minimize ischemic time.

The sequence of allocation has undergone revision to prioritize organs to the most critically ill heart transplant candidates (Table 5). In the 1999 revision, organs were offered to local Status 1A, 1B and 2 candidates before being offered to candidates in zones A, B or C. A consequence

Table 4: Comparison of historical and current heart allocation policies[1]

Component	Policies		
	1989–1999	1999	Current
Medical urgency	2-tiered, Status 1 and 2	3-tiered, Status 1A, 1B and 2	Status 1A, 1B and 2
Geographic sequence	Local, zone A, zone B, zone C	Local, zone A, zone B, zone C	Adult donors: OPO Status 1A, 1B; zone A Status 1A, 1B; local Status 2 (Figure 5). Pediatric donors: combined OPO and zone A Status 1A pediatric; OPO Status 1A adult; OPO + zone A Status 1B pediatric; OPO Status 1B adult; zone A Status 1A, zone A Status 1B (Figure 6).
ABO blood type	Identical/compatible not differentiated for Status 1; differentiated for Status 2, identical prioritized for Status 2	Primary ABO prioritized before secondary ABO within each Status category	Primary ABO prioritized before secondary ABO within each status category; allocation to candidates eligible to receive a heart from any blood type donor after allocation to all compatible blood types
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	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	May be on both heart and lung lists; lungs go with heart or heart goes with lungs if no Status 1A heart candidate	May be on both heart and lung lists; lungs go with heart or heart goes with lungs if no Status 1A heart candidate
Pediatric considerations	Age < 6 months may be Status 1	Separate urgency criteria, preference to pediatric recipient for adolescent donor	Separate urgency criteria, preference to pediatric candidate for pediatric donor
Sensitized patients	Local agreement	Local agreement	Local agreement
Monitoring issues	Status 1 random audits of ICU location	Regional review boards for assignment of status; random audits of justification forms	Regional review boards for exceptions to Status 1A and 1B; random audits for Status 1A and Status 1B justification forms

OPO = organ procurement organization.
Status 1, candidates requiring total artificial heart, left or right ventricular assist device, intraaortic balloon pump, ventilator, or in intensive care unit requiring inotrope therapy; Status 2, all other actively listed candidates. Geographic zones: Local, donation service area; zone A, < 500 nautical mile radius of donor hospital; zone B, 500-< 1000 miles; zone C, 1000–1500 miles; zone D, 1501–2500 miles; zone E > 2500 miles. Pediatric heart donor is defined as age < 18 years; pediatric heart candidate is defined as age < 18 years at the time of listing. Primary ABO compatibility includes all four identical combinations (O donor/O candidate, A donor/A candidate, B donor/B candidate, AB donor/AB candidate) and O donor/B candidate, A donor/AB candidate, and B donor/AB candidate; secondary ABO compatibility includes O donor/A candidate and O donor/AB candidate; ABO identical includes O donor/O candidate, A donor/A candidate; B donor/B candidate, AB donor/AB candidate; ABO compatible includes O donor/A, B, or AB candidate and A donor/O candidate, B donor/O candidate.
[1]Adapted from Renlund et al. (20).

of this allocation sequence was that local Status 2 candidates would be offered a compatible donor heart ahead of Status 1A or 1B candidates in zone A or B. The sequence was revised in 2006; under the new policy, hearts could be offered to Status 1A and 1B candidates in zone A before being offered to Status 2 local candidates. This policy change affected adult and young pediatric (ages 0–10 years) donor hearts.

In 2008, the Pediatric Transplantation Committee proposed a new allocation sequence to reduce wait-list mortality in younger patients and to expedite allocation of young donor hearts (ages 0–10 years) to pediatric patients. The new sequence, implemented in 2009, mandated that all pediatric donor offers be allocated first to combined local and zone A pediatric Status 1A candidates, then to local adult Status 1A candidates, then to combined local and zone A pediatric Status 1B candidates, before being offered to adult and pediatric candidates according to the prior algorithm (Table 5).

Blood group considerations

In the 1989 system, ABO identical and ABO compatible were considered equal for Status 1 patients. A Status 1 candidate whose blood group was identical to a donor's received the same consideration as a candidate whose blood group was compatible. For Status 2 candidates within a specified geographic zone, ABO identical received priority over ABO compatible. Consequently, waiting times for blood group O candidates increased substantially

Table 5: Evolution of the heart allocation sequence

January 1999–June 2006	Current Adult Heart Sequence[1]	Current Pediatric Heart Sequence
	1. OPO Status 1A ABO primary candidates	1. Combined OPO and zone A Status 1A ABO primary pediatric candidates for pediatric donor
1. Local Status 1A	2. OPO Status 1A ABO secondary candidates	2. Combined OPO and zone A Status 1A ABO secondary pediatric candidates for pediatric donor
2. Local Status 1B	3. OPO Status 1B ABO primary candidates	3. OPO Status 1A ABO primary candidates
3. Local Status 2	4. OPO Status 1B ABO secondary candidates	4. OPO Status 1A ABO secondary candidates
		5. OPO + zone A Status 1B ABO primary pediatric candidates for pediatric donor
	5. Zone A Status 1A ABO primary candidates	6. OPO + zone A Status 1B ABO secondary pediatric candidates for pediatric donor
	6. Zone A Status 1A ABO secondary candidates	7. OPO Status 1B ABO primary candidates
4. Zone A Status 1A	7. Zone A Status 1B ABO primary candidates	8. OPO Status 1B ABO secondary candidates
5. Zone A Status 1B	8. Zone A Status 1B ABO secondary candidates	9. Zone A Status 1A ABO primary candidates
	9. OPO Status 2 ABO primary candidates	10. Zone A Status 1A ABO secondary candidates
6. Zone B Status 1A	10. OPO Status 2 ABO secondary candidates	11. Zone A Status 1B ABO primary candidates
7. Zone B Status 1B	11. Zone B Status 1A ABO primary candidates	12. Zone A Status 1B ABO secondary candidates
	12. Zone B Status 1A ABO secondary candidates	13. OPO Status 2 ABO primary pediatric candidates for pediatric donor
8. Zone A Status 2	13. Zone B Status 1B ABO primary candidates	14. OPO Status 2 ABO secondary pediatric candidates for pediatric donor
	14. Zone B Status 1B ABO secondary candidates	15. OPO Status 2 ABO primary candidates
	15. Zone A Status 2 ABO primary candidates	16. OPO Status 2 ABO secondary candidates
	16. Zone A Status 2 ABO secondary candidates	17. Zone B Status 1A ABO primary pediatric candidates for pediatric donor
	17. Zone B Status 2 ABO primary candidates	18. Zone B Status 1A ABO secondary pediatric candidates for pediatric donor
9. Zone B Status 2	18. Zone B Status 2 ABO secondary candidates	19. Zone B Status 1A ABO primary candidates
	19. Zone C Status 1A ABO primary candidates	20. Zone B Status 1A ABO secondary candidates
	20. Zone C Status 1A ABO secondary candidates	21. Zone B Status 1B ABO primary pediatric candidates for pediatric donor
10. Zone C Status 1A	21. Zone C Status 1B ABO primary candidates	22. Zone B Status 1B ABO secondary pediatric candidates for pediatric donor
11. Zone C Status 1B	22. Zone C Status 1B ABO secondary candidates	23. Zone B Status 1B ABO primary candidates
12. Zone C Status 2	23. Zone C Status 2 ABO primary candidates	24. Zone B Status 1B ABO secondary candidates
	24. Zone C Status 2 ABO secondary candidates	25. Zone A Status 2 ABO primary pediatric candidates for pediatric donor
		26. Zone A Status 2 ABO secondary pediatric candidates for pediatric donor
		27. Zone A Status 2 ABO primary candidates
		28. Zone A Status 2 ABO secondary candidates
		29. Zone B Status 2 ABO primary pediatric candidates for pediatric donor
		30. Zone B Status 2 ABO secondary pediatric candidates for pediatric donor
		31. Zone B Status 2 ABO primary candidates
		32. Zone B Status 2 ABO secondary candidates
		33. Zone C Status 1A ABO primary pediatric candidates for pediatric donor
		34. Zone C Status 1A ABO secondary pediatric candidates for pediatric donor
		35. Zone C Status 1A ABO primary candidates
		36. Zone C Status 1A ABO secondary candidates
		37. Zone C Status 1B ABO primary pediatric candidates for pediatric donor
		38. Zone C Status 1B ABO secondary pediatric candidates for pediatric donor
		39. Zone C Status 1B ABO primary candidates
		40. Zone C Status 1B ABO secondary candidates
		41. Zone C Status 2 ABO primary pediatric candidates for pediatric donor
		42. Zone C Status 2 ABO secondary pediatric candidates for pediatric donor
		43. Zone C Status 2 ABO primary candidates
		44. Zone C Status 2 ABO secondary candidates

OPO = organ procurement organization.
Zone D was added in 2003 and zone E in 2007.
[1]At implementation, this policy applied to adult donors and young pediatric donors but not to adolescent donors. In May 2009, when the pediatric donor policy was modified, this policy applied only to adult donors.

between 1988 and 1995 (20). The 1999 revisions attempted to rectify this by prioritizing blood group O hearts first to blood group O or B recipients (primary ABO matching), irrespective of waiting time for other potentially compatible blood groups. Other primary ABO matching categories included the following: blood type A donors were prioritized to blood type A or AB recipients; blood type B donors to type B or AB recipients and blood type AB donors to type AB recipients. Other compatible pairs, O donor/A candidate or O donor/AB candidate, were considered secondary ABO matching pairs. This prioritization scheme applied to each urgency category and geographic zone. Policy for ABO-incompatible (ABO-I) heart transplant was established by OPTN in 2001 (25,26); hearts were allocated to infants aged <1 year listed for ABO-I heart transplant only if no ABO compatible candidate nationwide accepted the donor heart.

Current heart allocation policies

Current heart allocation policy reflects an effort to prioritize hearts to the sickest heart transplant candidates on the waiting list, while taking into account technological advances that have changed the clinical profile and prognosis. This is supported by recent revisions to the policy and ongoing proceedings attempting to provide more granularity to the current medical urgency criteria. US heart allocation policy is based on medical urgency, waiting time, blood group compatibility and geography. The most important recent revision to heart allocation policy occurred in 2006, when the geographic sequence was modified, prioritizing the most critically ill patients while taking into account optimal maximal ischemia time. Changing VAD technology and effective heart failure therapies have introduced a new level of medical and ethical complexity to the discussion of allocation policies, and the current policy is being reviewed and revisions considered that would reflect emerging technology and changing wait-list survival and posttransplant outcomes.

Medical urgency status (OPTN Policies 3.7.3 and 3.7.4)

Adult criteria: Adult heart transplant candidates qualify for a status code corresponding to medical urgency. Status 1A, the highest medical urgency code, has 4 subcategories (Table 6). Status 1A candidates must be admitted to the listing transplant center, except for LVAD/RVAD candidates, who qualify for 30 days as Status 1A (subcategory a (i)), and candidates with device complications (subcategory b). Status 1A candidates must meet one of the four criteria outlined in Table 6 (Policy 3.7.3).

Qualification for Status 1A under subcategories a–c (with the exception of a (i)) is valid for 14 days and must be recertified every 14 days from the time of initial listing. Qualification for Status 1A under subcategory d is valid for 7 days and must be recertified every 7 days. Centers are notified of the need for recertification and unless the criteria are recertified, candidates are automatically reclassified to Status 1B (9).

LVAD/RVAD candidates and candidates on continuous intravenous inotrope infusion who do not meet Status 1A criteria qualify for Status 1B. These candidates are not required to be admitted to the transplant center or to be using high-dose inotrope infusion. Candidates who do not meet criteria for Status 1A or 1B may be listed as Status 2. Those who are temporarily unsuitable for receiving an organ are listed as Status 7 (inactive) and will not receive organ offers.

Pediatric criteria: Pediatric candidates (aged <18 years) qualify for listing as Status 1A for 14 days under five criteria (Table 7). After 14 days from the initial listing, the candidate is automatically downgraded to Status 1B, unless the attending physician recertifies the 1A listing. A heart Status 1A justification form must be submitted to UNet^{SM} for new Status 1A candidates, and for extension of current Status 1A candidates. The pediatric policy is similar to the adult policy but provides two additional criteria: 1A (d) addresses candidates who qualify for Status 1A if they are infants aged <6 months with acquired or congenital heart disease and reactive pulmonary hypertension (>50% of systemic level); 1A (f) addresses candidates who qualify for Status 1A if the life expectancy is <14 days without heart transplant (e.g. refractory arrhythmia) and do not meet criteria for Status 1A (a), (b), (c), (d) or (e). Pediatric candidates who are receiving a single inotrope (dopamine or dobutamine) in low dosage, are aged <6 months and do not fulfill the criteria of Status 1A, or have growth failure (defined as <1.5 standard deviations of expected growth or greater than fifth percentile for height and/or weight) qualify as Status 1B. Candidates who do not meet criteria for Status 1A or 1B are listed as Status 2, and candidates who are temporarily unsuitable to receive a thoracic organ transplant are listed as Status 7. Pediatric heart transplant candidates who remain on the waiting list at the time of their eighteenth birthdays without having undergone heart transplant continue to qualify for medical urgency status based on the pediatric criteria. There is no policy requirement that pediatric candidates be hospitalized or receiving hemodynamic monitoring to qualify for Status 1A.

Status exceptions (OPTN Policy 3.7.3)

Candidates who do not meet criteria for Status 1A or 1B but have documented need for urgent listing may qualify for an exception. Transplant physicians must submit a status justification form to the RRB describing the rationale for the exception. Candidates may be listed as Status 1A or 1B by exception whereas the RRB reviews the status justification. If the RRB does not approve the exception, the physician may list the candidate as Status 1A or 1B while awaiting an appeal to the Thoracic Organ Transplantation Committee. Adult candidates considered for Status 1A

Table 6: Adult candidate status 1A and 1B (OPTN Policy 3.7.3)

Status	Subcategory	Qualifications	Comments
1A		Candidate should be admitted to the hospital where the heart transplant is to be performed and should be managed with one of the following therapies or devices:	
	(a)	MCS for acute hemodynamic decompensation and at least one of:	
		(i) LVAD/RVAD	Candidates may be listed for 30 days as 1A at any point, hospitalization not required.
		(ii) TAH	
		(iii) IABP	
		(iv) ECMO	Qualification under criterion 1A(a)(ii), (iii) or (iv) is valid for 14 days and must be recertified to extend 1A Status.
	(b)	MCS with objective medical evidence of significant device-related complications (infection, thromboembolism, ventricular arrhythmias, mechanical failure, other related complications) approved by heart RRB.	Admission to listing center not required.
	(c)	Continuous mechanical ventilation.	Qualification under criterion 1A(b) or (c) is valid for 14 days and must be recertified every 14 days to extend 1A Status.
	(d)	Continuous infusion of single or multiple inotropes in addition to hemodynamic monitoring.	Qualification under 1A(d) is valid for 7 days and must be recertified every 7 days to extend 1A Status.
1A exception		Candidates who do not meet the above criteria	Initial listing requires approval by the RRB and is valid for 14 days. Further extension requires review and approval by the RRB.
1B		At least one of the following devices or therapies:	
	(aa)	LVAD/RVAD	
	(bb)	Continuous infusion of intravenous inotropes	
1B exception		Does not meet the above criteria for 1B	Requires provision of justification and review by the RRB.

ECMO = extracorporeal membrane oxygenation; IABP = intraaortic balloon pump; LVAD/RVAD = left or right ventricular assist device; MCS = mechanical circulatory support; OPTN = Organ Procurement and Transplantation Network; RRB = Regional Review Board; TAH = total artificial heart.

exception must be admitted to the listing transplant hospital. The pediatric allocation policy incorporates language for exceptions to Status 1A under criterion (f). Listing under this criterion is valid for 14 days and does not require admission to the listing transplant center hospital. Further extension requires a conference with the RRB. If a pediatric candidate does not meet Status 1B criteria but is considered a 1B candidate, the transplant physicians can apply for and justify Status 1B listing to the RRB.

Waiting time (OPTN Policy 3.7.9)

Within each status category, allocation is based on waiting time. Waiting time is accrued while the candidate is listed as Status 1A, 1B and 2; however, time accrued at a lower status does not accrue toward time at a higher status. Specifically, all accrued time is applied while awaiting heart transplant as Status 2, but time accrued as Status 1A is applied only to 1A time, and time accrued as Status 1B is combined with 1A time for total 1B time. Therefore, a candidate on the waiting list for 3 weeks as Status 1A and never listed as Status 2 receives priority over a candidate who has waited for 2 weeks as Status 1A and has combined Status 1A and Status 2 time of 3 months. When applicable, time accrued on the waiting list for a single thoracic organ (heart or single lung) may also accrue for a second thoracic organ when the candidate requires a multiple thoracic organ transplant (heart–lung or double lung). Alternatively, time accrued for a multiple thoracic organ transplant (heart–lung) may be transferred to time for a single thoracic organ (heart only) (14).

Mechanical circulatory support

Adult candidates with MCS devices: Ventricular assist devices

Current OPTN thoracic organ allocation policy allows LVAD and/or RVAD patients to be listed as Status 1A for 30 days at any point after implantation once they are deemed clinically stable by the treating physician, without being admitted to the transplant facility (14; Policy 3.7.3). Candidates with objective evidence of MCS device-related complications can be listed as Status 1A, subcategory (b), without being admitted to the hospital. Centers may request exceptions for other complications (except sensitization) not described in the policy statement as justification for listing

Table 7: Pediatrics candidate status 1A and 1B (OPTN Policy 3.7.4)

Status	Subcategory	Qualification	Comments
1A		Candidates aged < 18 years at the time of listing qualify for Status 1A if one of the following criteria is met:	
	(a)	Ventilator	
	(b)	Mechanical assist device	
	(c)	IABP	
	(d)	Infant aged < 6 months with acquired or congenital heart disease and reactive pulmonary hypertension > 50% of systemic level	May be treated with prostaglandin E.
	(e)	High dose inotropes (e.g. dobutamine ≥ 7.5 mcg/kg/mn or milrinone ≥ 0.5 mcg/kg/mn) or multiple inotropes (e.g. addition of dopamine ≥ 5 mcg/kg/mn).	Qualification for 1A(a), (b), (c), (d) and (e) is valid for 14 days and requires recertification.
	(f) Exception	Does not meet above criteria but has a life expectancy without heart transplant of < 14 days (e.g. refractory arrhythmias)	Qualification for 1A(f) is valid for 14 days and may be recertified for one additional 14-day period; extensions beyond this require conference with the RRB.
1B		Candidate must meet at least one of the following criteria:	
	(a)	Infusion of low dose single inotropes	
	(b)	Aged < 6 months and does not meet criteria for Status 1A	Growth failure is defined as defined as loss of 1.5 standard deviations of expected growth (height or weight) or < 5th percentile for height and/or weight.
	(c)	Growth failure	
1B exception		Does not meet above criteria for Status 1B	Requires provision of justification and review by the RRB.

IABP = intra-aortic balloon pump; OPTN = Organ Procurement and Transplantation Network; RRB = regional review board.

as Status 1A. These requests are subject to review by the respective RRB (14; Policy 3.7.3).

Total artificial heart. The policy implemented in 1999 classified inpatient heart transplant candidates with TAHs as Status 1A. Once discharged, however, these candidates no longer qualified as Status 1A but could be listed as Status 1B. This policy did not address outpatient TAH candidates, as this patient population did not exist until recently. The Thoracic Organ Transplantation Committee thus proposed an interim policy that allows for the accrual of 30 days of Status 1A time at any point after discharge for a TAH candidate, similar to the VAD policy. This policy was approved by the OPTN Board of Directors and implemented in November 2010. Candidates with TAHs can qualify for an unlimited amount of Status 1A time, a provision that remains contentious because the total Status 1A time that can be accrued by an LVAD and/or RVAD candidate without complications is 30 days. As of this writing, the current revision to the TAH policy will expire in December 2012 (14).

Pediatric candidates with MCS devices: Pediatric candidates with MCS, including ECMO, VADs and TAHs, are eligible to be listed as Status 1A indefinitely with recertification every 14 days under criteria (b) (Table 7). Because all pediatric candidates with MCS are eligible under this criteria, the pediatric heart policy does not specifically address VAD-related complications or infections.

Geographic Sequence (OPTN Policy 3.7.2)

Adult donors: In 2006, OPTN began prioritizing zone A Status 1A and 1B candidates ahead of local Status 2 candidates (Table 5). This revision was intended to reduce the death rate on the waiting list. Despite an increase in wait-list mortality between 2007 and 2008, wait-list mortality decreased overall from 199 deaths per 100 patient-years at risk in 1999 to 170 in 2008 (27). Thus, the policy change appeared, in part, to have favorably influenced wait-list mortality.

The policy change also resulted in a higher proportion of candidates undergoing transplant as Status 1A and 1B. The wider geographic sharing promoted by this policy raised concerns regarding decreased posttransplant survival, due to potentially longer ischemia times and more procedures in more urgent recipients; however, 1-year survival after this policy was implemented was not adversely affected, based on OPTN/SRTR data as of October 2010.

Heart allocation accounts for medical urgency while optimizing geographic distribution to reduce ischemia time. Allocation begins within the DSA and expands according

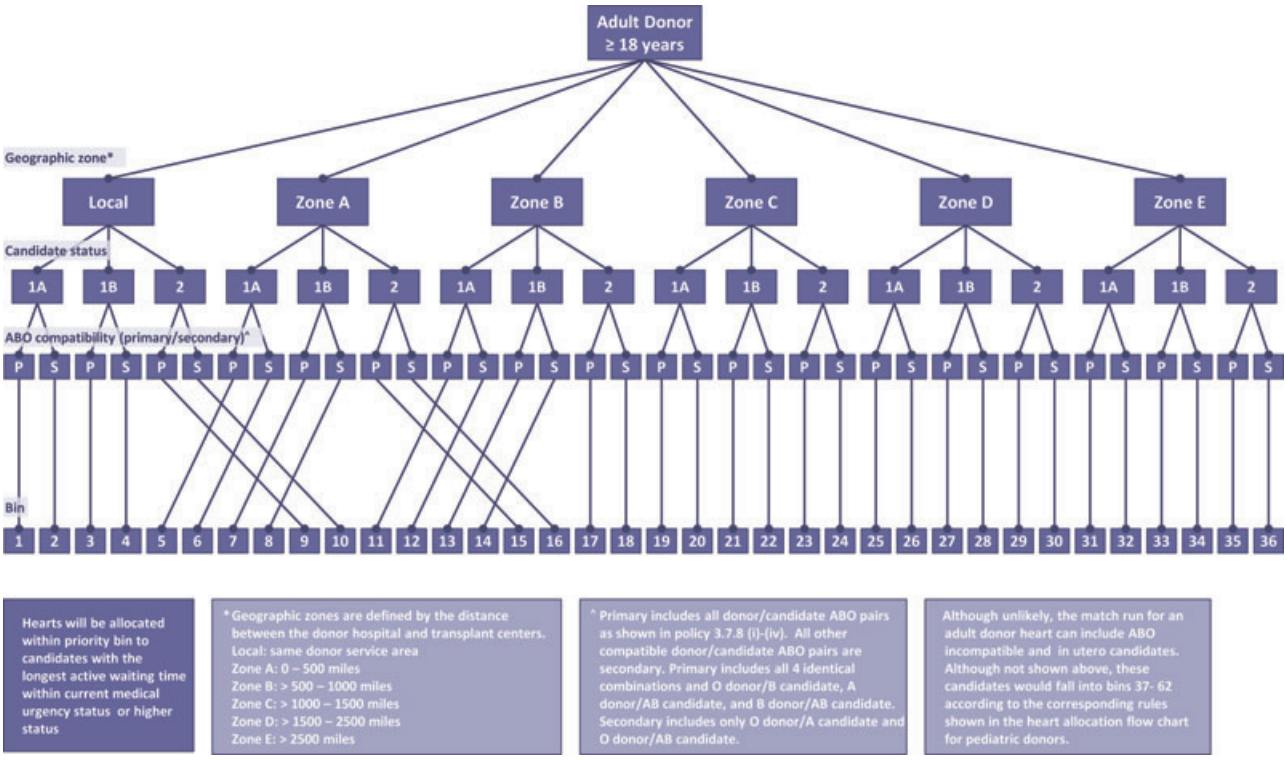

Figure 5: Allocation of hearts from adult (ages ≥ 18 years) donors. This figure can be downloaded in color from www.srtr.org.

to geographic zones defined by concentric circles of 500 nautical mile radii from the donor recovery hospital as follows: zone A, 0–500 miles; zone B, >500–1000 miles; zone C, >1000–1500 miles; zone D, >1500–2500 miles; zone E, >2500 miles. A donor heart is first offered locally to Status 1A (Figure 5, bins 1 and 2) or 1B (bins 3 and 4) candidates. Within each status category, hearts are allocated first to candidates with primary ABO matches and subsequently to secondary blood types. If the organ is not accepted for a compatible recipient, it is offered to zone A Status 1A (bins 5 and 6) or 1B (bins 7 and 8) candidates. If there is no zone A recipient, the offer reverts to the DSA for local Status 2 candidates (bins 9 and 10). If there is no compatible recipient, the organ is offered to zone B Status 1A (bins 11 and 12) or 1B (bins 13 and 14) candidates. If there is no compatible recipient, the organ is offered to zone A Status 2 (bins 15 and 16) candidates. If there is no compatible recipient, allocation proceeds as follows: zone B, Status 2 (bins 17 and 18); zone C, Status 1A, 1B or 2 (bins 19–24); zone D, Status 1A, 1B or 2 (bins 25–30); zone E, Status 1A, 1B or 2 (bins 31–36). Thus, in this sequence, Status 1A or 1B candidates in the subsequent region precede Status 2 candidates in the preceding region up to zone B (OPTN Policy 3.7.8; Figure 5).

Pediatric donors: Current pediatric heart allocation policy preferentially allocates pediatric donor hearts to pediatric candidates. Consistent with the broader sharing policy, offers for pediatric donor hearts are initially made to pediatric candidates within the combined local DSA and zone A region for Status 1A candidates with preference for primary ABO matching (Figure 6A, bins 1 and 2). If the heart is not accepted for a pediatric candidate, it is offered to local Status 1A adults (bins 3 and 4). If there is no compatible Status 1A recipient, the organ is offered to Status 1B pediatric candidates within the combined DSA and zone A region (bins 5 and 6), and subsequently to Status 1B adults within the OPO (bins 7 and 8). If there is no compatible recipient, the heart is offered to Status 1A and 1B adult candidates within zone A (bins 9–12). Allocation then proceeds to candidates as follows: OPO Status 2 pediatric and adult (bins 13–16), zone B Status 1A pediatric then adult (bins 17–20), zone B Status 1B pediatric then adult (bins 21–24); zone A Status 2 pediatric then adult (bins 25–28); zone B Status 2 pediatric then adult (bins 29–32). Allocation to candidates in zones C–E proceeds in order of medical urgency with pediatric candidates first within each Status category and preference to primary ABO compatibility (bins 33–68).

ABO considerations (Policy 3.7.8)

Very young pediatric candidates (aged ≤14 months) are unique in their potential to accept an ABO-I donor heart because isohemagglutinins (anti-A and anti-B antibodies) develop late in infancy (28,29). In 2006, OPTN approved

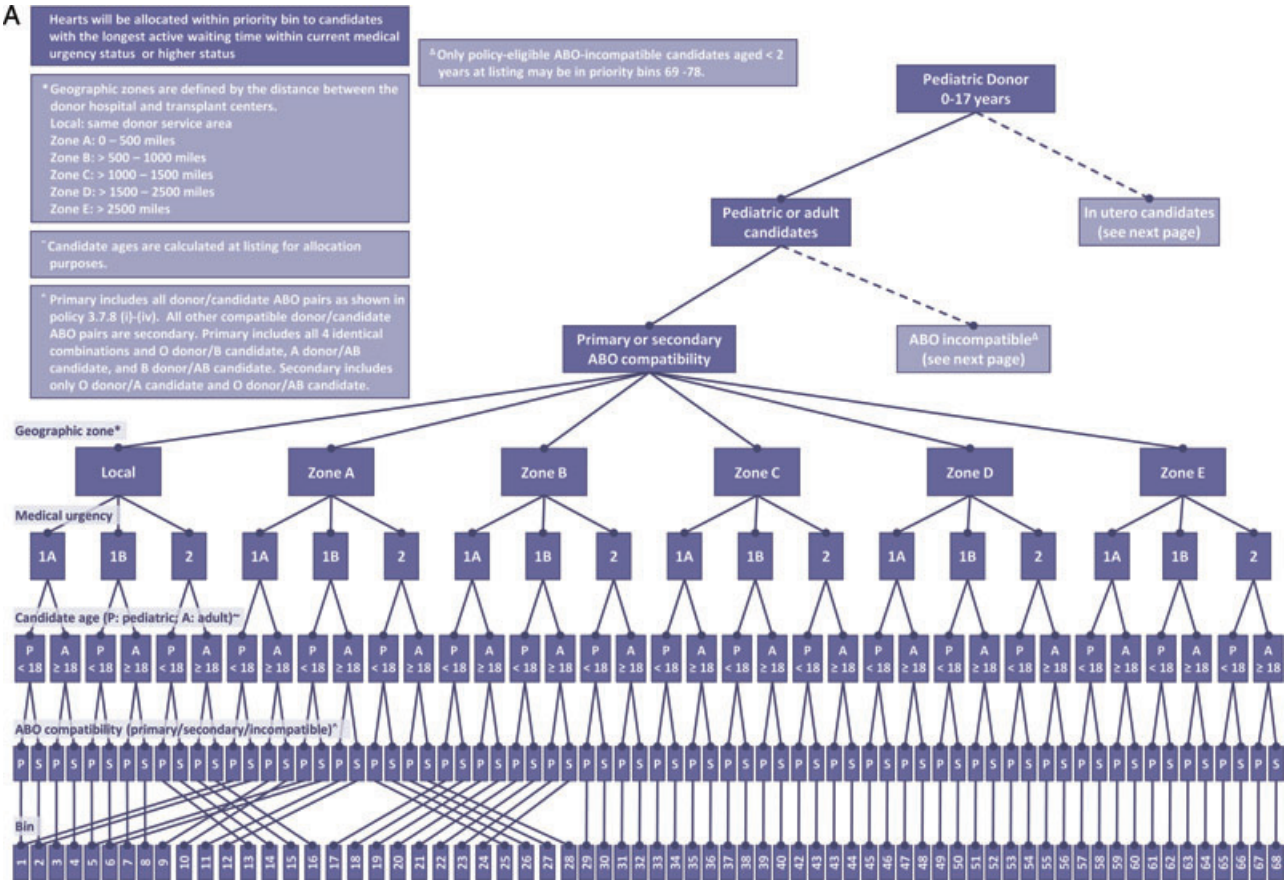

Figure 6: Allocation of hearts from pediatric (ages 0–17 years) donors, (A) bins 1–68 and (B) bins 69–93. This figure can be downloaded in color from www.srtr.org.

ABO-I heart transplant in children added to the waiting list before their second birthdays and meeting certain conditions (30). This policy was implemented in 2010. As a result, in 2007 the proportion of eligible infants aged <6 months listed for ABO-I heart transplant was 53% (31). Before a donor heart is allocated to an ABO-I candidate, the list of born (postnatal) ABO-compatible recipients must be exhausted (Figure 6A, bins 1–69). The donor heart is allocated first to Status 1A and 1B ABO-I pediatric candidates in the combined OPO and zone A region (Figure 6B, bins 69 and 70), then to local Status 2 pediatric ABO-I candidates (bin 71), then to Status 1A and 1B pediatric ABO-I candidates in zones B–E (bin 72–79). If no compatible candidates are eligible for ABO-I transplant, the heart is allocated to *in utero* candidates. Under current policies, to qualify for an ABO-I donor heart, a candidate must be (1) *in utero*; (2) aged <1 year and listed as Status 1A or 1B or (3) aged ≥1 year but listed before age 2 years and currently listed as Status 1A or 1B. For candidates aged ≥1 year, current isohemagglutinin titer must be ≤1:4 for A or B blood type antigens and the candidate must not have received treatments within the prior 30 days that may have reduced titer values to ≤1:4 (Policy 3.7.8).

Heart–lung allocation (Policy 3.7.7)

Between 2000 and 2011, 399 simultaneous heart–lung transplants were performed. In January 2011, the Thoracic Organ Transplantation Committee encouraged thoracic transplant programs to list candidates who require simultaneous heart–lung transplant for both organs according to listing policies governing each organ individually, and to list them on the heart–lung waiting list. Priority for a heart–lung transplant candidate on the lung transplant waiting list is determined by the LAS (for candidates aged ≥12 years), and on the heart waiting list by medical urgency status code as described earlier. When a donor heart becomes available to an eligible candidate, the lung is allocated from the same donor. When the candidate is eligible to receive a lung, the heart is allocated from the same donor only if no suitable Status 1A isolated heart candidates are eligible to receive the heart.

ABO matching requirements are determined by which organ match run the candidate is included in; ABO matching policy for heart allocation is used if the candidate is included in the heart match run, and for lung allocation if in the lung match run.

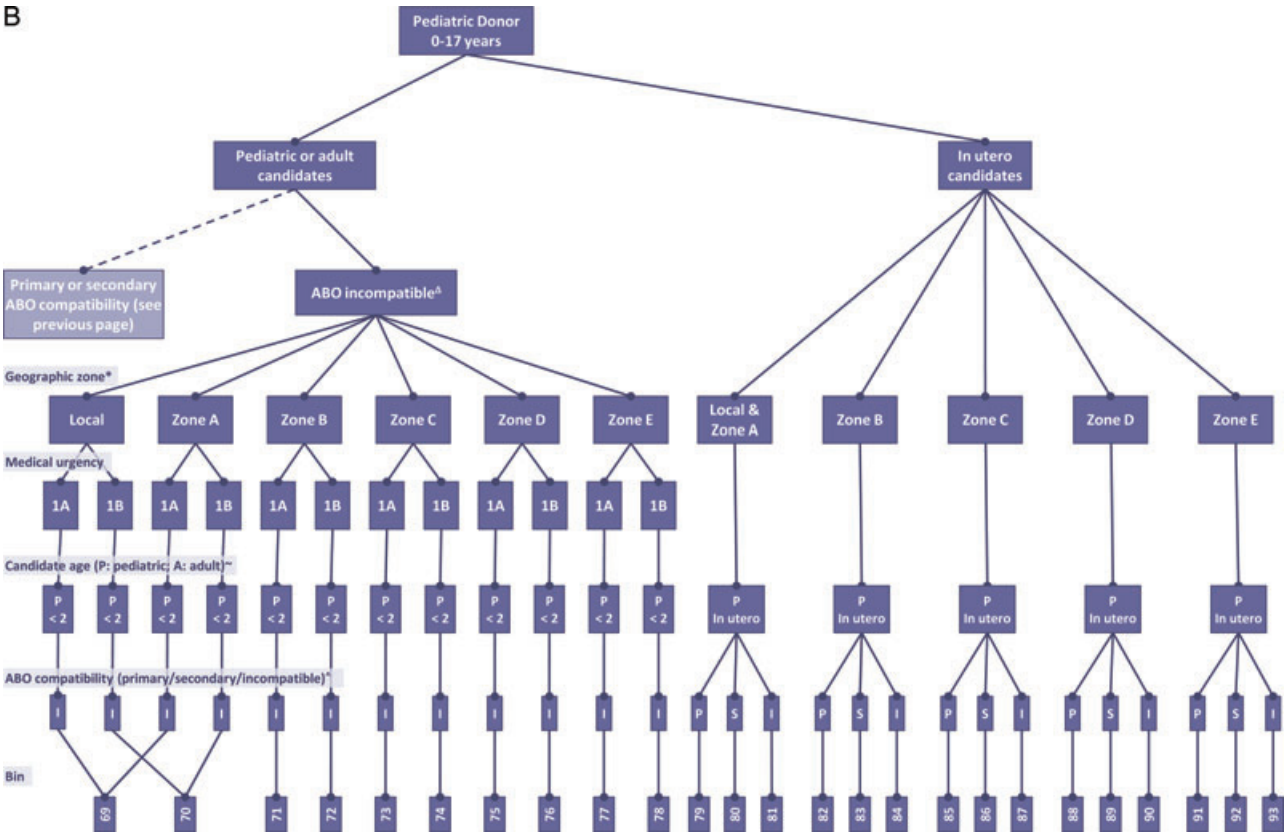

Figure 6: Continued.

Allocation of domino donor hearts (Policy 3.7.15)

Domino heart transplant refers to procurement and transplant of the native heart of a combined heart–lung transplant recipient. When a domino heart is available, it is first offered to candidates at the transplant center from which the native heart was procured. If the program does not use the heart, it is allocated based on the general heart policy or an approved variance. Only one domino heart transplant procedure has been performed in the United States since 1997.

Comparison to international heart allocation policies

Most heart allocation policies throughout the international transplant community are based on medical urgency with waiting time being a secondary feature (Table 8). Similar to the US allocation policies, algorithms are based on geography, which in some countries may extend to neighboring countries. For instance, if no country within the Scandiatransplant community has a suitable donor, a donor heart may be allocated to a recipient in another European country through an international exchange program. In general, heart transplant candidates appear to be grouped into urgent and nonurgent categories in several international allocation schemes. Similar to trends in the United States, a growing proportion of candidates are listed in the high-urgency category, similar to UNOS Status 1A, following revision of the Eurotransplant allocation policy in 2000 and 2005, which provided for a high urgency category in addition to an urgent category (32–34). Furthermore, candidates who receive VADs (excluding nondurable mechanical support such as ECMO or IABP) are removed from the urgent category unless they develop VAD-related complications, a policy similar to that in the United Kingdom and countries in the Scandiatransplant program (35,36). Scandiatransplant policy will consider candidates aged less than 16 years and with an LVAD for more than 1 year as high-urgent status (Priority 0) (37). The Canadian Cardiac Transplant Network allocation system promotes nationwide allocation. The allocation algorithm has six categories, with Status 4 being the highest urgency category. (Table 8) Hearts are allocated using a nationwide list, although priority is given to the region where the donor heart becomes available. When there are competing potential recipients, the recipient with the longest current listing as Status 4 is given priority. Similar to other international policies, candidates with VADs are listed in the highest urgency category when complications occur. Otherwise, candidates with VADs are listed as Status 3 (38). These international allocation policies could help inform discussions about future heart allocation policy in the United States.

Table 8: Examples of international heart allocation policies

Country	Policies
Canadian Cardiac Transplant Network (38)	Status 4: (1) Mechanically ventilated patient on high-dose single or multiple inotropes ± mechanical support (e.g. IABP, ECMO, abiomed BVS5000 or biomedicus), excluding VAD. (2) Patient with VAD malfunction or complication, such as thromboembolism, systemic device-related infection, mechanical failure or life-threatening arrhythmia. (3) Patient should be reconfirmed every 7 days as a Status 4 by a qualified physician if still medically appropriate. Status 4S: (1) High PRA (> 80%), or PRA > 20% with three prior positive crossmatches (in the setting of negative virtual or actual donor/recipient-specific crossmatch and appropriate size and blood type of the prospective donor). Status 3.5: (1) High-dose or multiple inotropes in hospital, and patients not candidates for VAD therapy or no VAD available. (2) Acute refractory ventricular arrhythmias. Status 3: (1) VAD not meeting Status 4 criteria. (2) Patients on inotropes in hospital, not meeting above criteria. (3) Heart/lung recipient candidates. (4) Cyanotic congenital heart disease with resting saturation < 65%. (5) Congenital heart disease, arterial-shunt dependent. (6) Adult-sized complex congenital heart disease with increasing dysrhythmic or systemic ventricular decline. Status 2: (1) In-hospital patient, or patient on outpatient inotropic therapy not meeting the above criteria. (2) Adult with cyanotic CHD: resting 02 saturation 65%-75% or prolonged desaturation to <60% with modest activity (i.e. walking). (3) Adult with Fontan palliation with protein-losing enteropathy or plastic bronchitis. (4) Patients listed for multiple organ transplantation (other than heart–lung). Status 1: All other out-of-hospital patients
Eurotransplant community[1] (32–34)	Each EU country has a unique algorithm. Heart allocation policy generally based on medical urgency. Major difference from US policy is that candidates with VAD are not automatically considered candidates for urgent heart transplant. Once a VAD is implanted, patient loses urgent status. If a patient with a VAD (irrespective of medical urgency for heart transplant) develops VAD-related complications, status for heart allocation is changed to urgent. Criteria for urgency status include: 1. Continuous IV inotropic therapy. 2. Assist device complications. 3. Documented intractable recurrent ventricular rhythm disorders. 4. End-stage transplant vasculopathy. 5. Persisting angina pectoris.
Scandiatransplant[2] (37) countries	Donor hearts used locally among patients labeled priority 0 (high urgent). If a member country lacks a priority (0/1) patient, a donor heart is provided to a patient labeled priority 2 in the region. If all member countries lack a suitable recipient, the donor heart is provided to other European countries through European organ-exchange organizations. Priority classifications: 0: ECMO, centrifugal pumps, blood pumps (implantable) with uncontrollable infection or device failure; patients aged < 16 years on LVADs for more than 1 year or on inotropes. Patient status renewed weekly. 1: This classification not used for heart transplant. 2: Patients who are transplantable. 3: Patients who are not transplantable.
United Kingdom Transplant Services Authority (36)[3]	Heart-allocation policies in the United Kingdom and Ireland are based on principles of biological matching, clinical priority, logistical factors such as ischemia time, prior sternotomies, adult congenital heart disease (ACHD), prior VADs etc. and fairness (time on waiting list) (19). Uses urgent heart allocation scheme. Candidates on the nonurgent waiting list are allocated hearts when there are no suitable candidates on the urgent list. Urgent status includes use of high-dose continuous inotropes, IABPs (with or without inotropes), short-term MCS (e.g. venoarterial ECMO), long-term VADs and device-related complications.

CHD = coronary heart disease; ECMO = extracorporeal membrane oxygenation; IABP = intraaortic balloon pump; LVAD = left-ventricular assist device; MCS = mechanical circulatory support; PRA = panel reactive antibody; VAD = ventricular assist device.
[1]Netherlands, Germany, Austria, Belgium, Croatia, Germany, Slovenia.
[2]Denmark, Finland, Norway, Sweden.
[3]United Kingdom and Ireland.

Future directions

Adult heart allocation policy: Current heart allocation policy attempts to prioritize allocation to the sickest candidates. As evidenced by recent revisions to the TAH policy, the policy is dynamic, allowing for adaptation in response to the latest technological and medical innovations, and the changing transplant candidate population. There is controversy over whether candidates with VADs, who are now stabilized, should continue to receive 30 days of Status 1A time and a potential listing advantage over sicker patients (39). Compared with older VADs, newer-generation VADS produce fewer complications and can effectively treat heart failure for extended periods; thus this policy may no longer be necessary. In its effort to revise the adult heart Status 1A policy, the OPTN/UNOS Thoracic Organ Transplantation Committee is considering changing the length of time a VAD candidate would receive Status 1A time. Thirty days is arbitrary, and how long a VAD candidate should receive Status 1A time may depend on factors such as the type of VAD. These data are being evaluated and will inform planned future policy change. The OPTN/UNOS Thoracic Organ Transplantation Committee is revising criterion (b), which allows clinicians to classify adult heart transplant candidates experiencing MCS device complications as Status 1A. The goal of this revision is to more clearly define what constitutes VAD complications to prioritize the sickest VAD patients.

Policy revisions may also consider candidates who are disadvantaged by the current listing process due to cardiomyopathies for which VADs or inotropes are contraindicated. As VAD survival improves, it may be prudent to consider prioritizing patients who are unable to benefit from VADs. Finally, many heart transplant professionals question the continued appropriateness of the Status 2 category. One-year survival of Status 2 candidates approaches that of heart transplant recipients, suggesting that early listing of adults may no longer be justified (27). Furthermore, waiting times for Status 2 candidates have risen dramatically in recent years. The median time to transplant for a Status 2 candidate on the waiting list in 2010–2011 was 17.6 months, compared with 1.7 months for Status 1A and 5.5 months for Status 1B (based on SRTR data as of March 15, 2012). In some regions, wait-list survival of Status 2 candidates may exceed the projected survival benefit of heart transplant (40).

A new allocation scheme predicated on evidence-based markers of disease severity and outcomes is being considered. The Heart Subcommittee of the OPTN Thoracic Organ Transplantation Committee is currently considering revising the entire policy (Policy 3.7.3) to better address medical urgency and disease severity in candidates with MCS devices. These revisions are expected to specify definitions of MCS-related infections and complications to provide more guidance and consistency in assigning medical urgency subcategories.

In January 2011, OPTN began collecting data on MCS devices at the time a candidate is removed from the waiting list. These and other analyses are being reviewed to more accurately address the clinical heterogeneity among candidates with MCS devices. The revised allocation system may account for posttransplant survival and wait-list mortality as indicators of disease severity (41).

Pediatric heart allocation policy

The Heart Subcommittee, the Thoracic Working Group of the Pediatric Committee and investigators from the Pediatric Heart Transplant Study, an international registry of pediatric heart transplant candidates and recipients, have evaluated revisions to current heart allocation policies that will address medical urgency categories, *in utero* listings, and ABO-I transplant. *In utero* listings are rare, and at its April 2011 meeting the Pediatric Transplantation Committee voted unanimously to submit for public comment a proposal to eliminate all policies allowing *in utero* listings (42). Also, in light of data demonstrating that ABO-I transplants may be performed safely at isohemagglutinin titers higher than 1:4, proposals for a new titer threshold for ABO-I transplant are being considered. Finally, a proposal for revising medical urgency categories for pediatric candidates is in development, with a goal of reducing wait-list mortality in the highest risk groups. Under the current system, most pediatric heart candidates, particularly infants, are listed as Status 1A at the time of transplant, in effect changing the allocation process to one based on time rather than medical urgency. Current policy may disadvantage certain patients, such as infants with restrictive cardiomyopathy and hypertrophic cardiomyopathy. A revised pediatric heart policy is anticipated for public comment distribution in 2012. Proposed revisions will specifically address listing criteria for candidates with congenital heart disease (41).

Heart–lung policy

The current heart–lung allocation policy does not address the potential occurrence of a tie, in which 2 heart–lung candidates are eligible to receive the same heart–lung bloc in the same geographic area. Further, the current policy does not address geography, Status 1B candidates, or sick lung transplant candidates also in need of heart transplants. The Policy Oversight Committee is currently developing principles for multiorgan allocation that will be considered by the Thoracic Organ Transplantation Committee in the development of modifications for this policy.

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Disclosure

The authors of this manuscript have conflicts of interest to disclose as described by the *American Journal of Transplantation*: By virtue of employment at or affiliation with a transplant program or an organization with an interest in transplant program performance, any author of this manuscript could be perceived to have a conflict of interest. Beyond that, no author has any conflict of interest to disclose as described by the *American Journal of Transplantation*.

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