OPTN/UNOS Thoracic Organ Transplantation Committee

Proposal to Modify the Adult Heart Allocation System

Prepared by:
Liz Robbins Callahan, Esq.
UNOS Policy Department

Proposal to Modify the Adult Heart Allocation System

Executive Summary

The Thoracic Organ Transplantation Committee (the Committee) proposes modifications to the adult heart allocation system to better stratify the most medically urgent heart transplant candidates, reflect the increased use of mechanical circulatory support devices (MCSD) and prevalence of MCSD complications, and address geographic disparities in access to donors among heart transplant candidates. Though changes to the adult heart allocation system implemented in 2006 were successful, candidates with disparate waiting list mortalities are currently grouped together in the most urgent classification, status 1A, causing waiting time to be the primary factor in stratifying candidates. Additionally, the current geographic sharing scheme creates potential inequities in access to transplant for the most urgent candidates.

The Committee proposes two significant changes to the adult heart allocation system:

1) Develop additional urgency stratifications based on relative waiting list mortality rates for all adult heart candidates
2) Modify the geographic sharing scheme to provide the most medically urgent candidates access to donors from a broader geographic area

The Committee's proposal is supported by modeling analysis performed by the Scientific Registry of Transplant Recipients (SRTR). The proposed changes are expected to lower waiting list morality rates overall and achieve higher transplant rates for the most medically urgent candidates without increasing overall post-transplant mortality rates or increasing waiting list mortality rates for candidates in lower urgency statuses.

Is the sponsoring Committee requesting specific feedback or input about the proposal?

1. Do you support the proposed status criteria?
2. Do you support the proposed geographic sharing scheme? Do you support the retention of the DSA as a unit of allocation for hearts?
3. Do you support the concept of requiring CPRA to be entered for candidates upon registration and removal?

Proposal to Modify the Adult Heart Allocation System

Affected Policies: Policy 3.7.B: Required Expedited Modifications of Waiting Time, Policy 6.1: Status Assignments and Update Requirements, Policy 6.1.A: Adult Heart Status 1A Requirements, Policy 6.1.B: Adult Heart Status 1B Requirements, Policy 6.1.C: Adult Heart Status 2 Requirements, Policy 6.2: Status Updates, Policy 6.3: Adult and Pediatric Status Exceptions; Policy 6.3.A: RRB and Committee Review of Exceptions, Policy 6.3.B: Exceptions to Allocation for Sensitized Candidates, Policy 6.4: Waiting Time, Policy 6.5.C: Sorting Within Each Classification, Policy 6.5.D: Allocation of Hearts from Donors at Least 18 years Old, Policy 6.5.E: Allocation of Hearts from Donors Less Than 18 Years Old, and Policy 6.5.F: Allocation of Heart-Lungs

Sponsoring Committee: Thoracic Organ Transplantation Committee

Public Comment Period: January 25, 2016 – March 25, 2016

What problem will this proposal solve?

Since the last significant revision to the adult heart allocation system in 2006 there has been an overall decline in waiting list mortality rates among adult heart transplant candidates, and specific patient groups intended to benefit from the previous policy changes experienced the most substantial decline in mortality rates. The Committee acknowledged the success of the 2006 policy modifications, but ultimately determined that there are candidate groups disadvantaged by the current system for various reasons, such as their diagnosis, the way their physician chooses to treat their condition, or because of geographic location. The Committee determined there are four major problems with the current system:

1) Too many status 1A candidates
2) Too many exception requests required
3) Increased use of MCSDs not accommodated by current system
4) Geographic sharing scheme is inequitable

Too Many Status 1A Candidates

First, since 2006, the number of active heart transplant candidates more than doubled from 1,203 candidates on July 31, 2006 to 3,008 candidates on November 30, 2015. During that same time period, the number of status 1A candidates increased 548 percent, from 58 to 376, and the number of status 1B candidates increased 580 percent, from 255 to 1,734. By 2014, sixty-seven percent of adult heart transplants (2,251) were performed for patients that were status 1A at time of transplant. Candidates registered as status 1A are three times more likely to die on the waiting list than candidates in any other status. The current system therefore requires more granular stratification in order to ensure that candidates in most need have access to donor hearts first.

Too Many Exception Requests Required

Second, some candidate groups, such as candidates diagnosed with amyloidosis or congenital heart disease, are not served well by the current system and often must request exceptions. Between July 2009 and June 2011, members submitted 640 status 1A exception requests on behalf of 400 candidates, and 310 status 1B exception requests on behalf of 255 candidates. Depending on exceptions is not optimal for the patient, because exception requests must be approved by a regional review board, leading to the potential for variability dependent upon the region in which the request was made. The proposed

policy better accounts for relative waiting list mortality rates of all candidate groups, including those candidates currently forced to apply for policy exceptions, and treats these patients more equitably.

Increased Use of MCSDs Not Accommodated by Current System

Third, medical practice in the heart transplant community has also evolved since 2006; use of MCSDs has increased significantly, though disparately depending upon geography. In 2007, only 16.2 percent of candidates were first registered under an MCSD-related criterion; by 2014, that percentage increased to 35.8 percent. Increased use of MCSDs is associated with more complications associated with the MCSDs, often requiring urgent transplantation. The proposed system better stratifies candidates based on the type of MCSD support and the risks associated with specific device complications.

Geographic Sharing Scheme is Inequitable

Lastly, the current geographic sharing scheme is not consistent with the OPTN Final Rule, which states that organ allocation policies "[s]hall not be based on the candidate's place of residence or place of listing…"[1] The current geographic sharing scheme is inequitable, as it favors less urgent candidates locally in the local DSA rather than more urgent candidates who may be as close as 25 miles away from the donor but are in Zone A. The proposed policy modifies the current geographic sharing scheme to ensure the most urgent candidates have access to donors in a broader geographic area.

Why should you support this proposal?

The proposed policy resolves the problems outlined above by better distinguishing and prioritizing candidates based on urgency and by reflecting the conditions of a wider range of heart transplant candidates than the current system. The Committee attempted to incorporate physiological principles into the criteria that were previously based on clinical consensus and subjective patient management decisions, and not clearly stated in policy. It also increases access to the donor pool for candidates most urgently in need of transplant. Most importantly, this proposal is expected to provide timely access to transplant for candidates most in need without negatively impacting candidates that may be able to wait longer for transplant.

How was this proposal developed?

The current adult heart allocation system stratifies active candidates into three medical urgency statuses: status 1A; status 1B, and status 2. Candidates are considered adults if they are registered on the waiting list at age 18 years or older. Candidates qualify for status 1A, if:

- they require continuous infusion of a single high-dose intravenous inotrope or multiple intravenous inotropes and continuous hemodynamic monitoring
- they are supported by a total artificial heart, an intra-aortic balloon pump (IABP), extracorporeal mechanical oxygenation (ECMO), mechanical ventilation, or a ventricular assist device (VAD) (for a 30 day discretionary period)
- they are implanted with a MCSD and are experiencing a device-related complication
- they have an approved exception

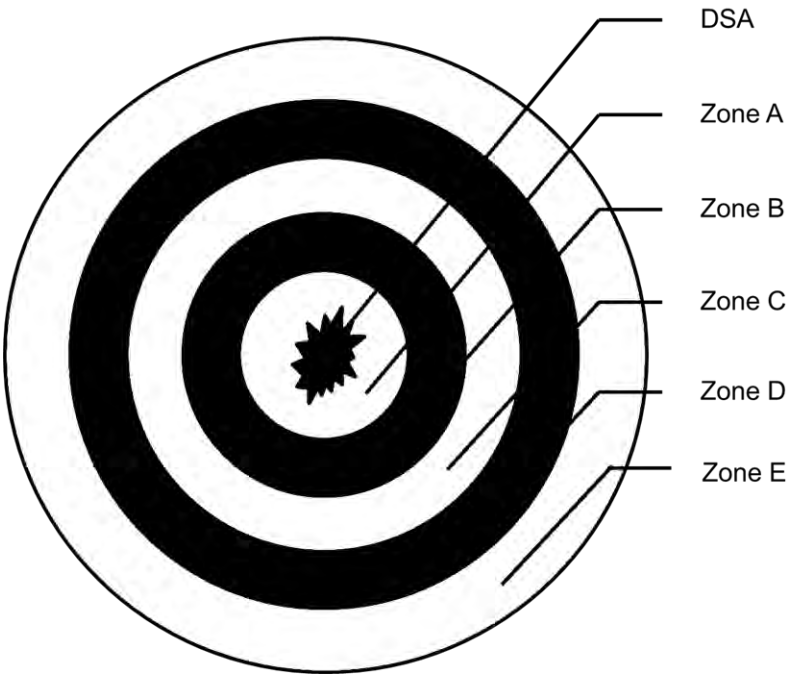
Candidates that are stable but supported by a VAD or that require continuous infusion of intravenous inotropes and do not meet the criteria for status 1A qualify for status 1B. Candidates that are in need of a heart transplant but do not meet status 1A or 1B qualifying criteria qualify for status 2.

[1] OPTN Final Rule §121.8(a)(8) http://www.ecfr.gov/cgi-bin/text-idx?SID=bb60e0a7222f4086a88c31211cac77d1&mc=true&node=pt42.1.121&rgn=div5#se42.1.121_14

Geographic allocation depends on the location of the donor. **Figure 1** demonstrates the zonal structure for allocation of thoracic organs. The DSA (donation service area) is the starting point, and is the geographic area designated by the Centers for Medicare and Medicaid Services (CMS) that is served by one organ procurement organization (OPO), one or more transplant hospitals, and one or more donor hospitals. DSAs are not uniformly shaped and may differ substantially in terms of land mass or area. There are 58 across the country.

Zone A includes all transplant hospitals within 500 miles of the donor hospital but outside of the donor hospital's DSA; Zone B includes all transplant hospitals within 1,000 miles of the donor hospital but outside of Zone A and the donor hospital's DSA; Zone C includes all transplant hospitals within 1,500 miles of the donor hospital but outside of Zone B and the donor hospital's DSA; Zone D includes all transplant hospitals within 2,500 miles of the donor hospital but outside of Zone C; and finally Zone E includes all transplant hospitals more than 2,500 miles from the donor hospital.

Figure 1: Zones Used for Thoracic Organ Allocation



In the current allocation system, organs recovered from deceased donors aged 18 years or older are first offered to status 1A candidates "locally" within the donor hospital's DSA and then to status 1B candidates locally. If not accepted locally, the heart is then offered to status 1A candidates in Zone A, and then to all status 1B candidates in Zone A. Only after offers are made through Zone A status 1B candidates is the heart then offered to a local status 2 candidate. Allocation then continues through subsequent geographic zones.

The Committee defined its goals in modifying the adult heart allocation system:

1) Reduce waiting list mortality rates
2) Reduce the use of exceptions to qualify for a status by better accommodating all candidate groups within the heart allocation system
3) Ensure that qualifying criteria for the statuses are based on objective physiological indications rather than therapeutic intervention
4) Improve overall access to transplantation in the heart allocation system by modifying geographic distribution to ensure maximum utility of donor hearts

To achieve the stated goals, the Committee debated three potential solutions:

- Retain the current three-status system
- Develop a heart allocation score
- Develop additional statuses

The Committee considered retaining the current three-tiered system but refining the qualifying criteria for each of the statuses. This idea was quickly dismissed, because it is clear based on the number of exception requests and disparate waiting list mortality rates for candidates in status 1A that the adult heart candidate pool is too diverse to be stratified effectively by so few statuses.

In 2012, the OPTN/UNOS Board of Directors charged the Thoracic Organ Transplantation Committee (the Committee) to "consider replacing the heart status system with a heart allocation score."[2] The Committee debated the merits of developing a heart allocation score (HAS). It acknowledged that a HAS may eventually be the best method for accounting for post-transplant survival and net benefit. However, the OPTN does not currently collect all the data necessary to develop a HAS at this time. Additionally, the Committee was concerned that the HAS is not a flexible solution. This would be particularly problematic for the heart transplant community, as technology is changing quickly and may affect the outcomes of subgroups of patients and invalidate the HAS. The Committee agreed that VAD technology in particular is evolving rapidly and may exceed the ability of a HAS to account for new devices and complications.

Based on these considerations, the Committee ultimately opted to develop additional statuses to better stratify heart transplant candidates while prospectively collecting additional data that may be necessary for developing a heart allocation score in the future, if the Committee decides to do so. The Committee agreed that adding more statuses to the current system may better accommodate the speed at which technology changes, because if a patient group is suddenly doing much better or much worse, moving those patients among the statuses can be done more quickly than changing a HAS system.

Development of Additional Statuses

To develop additional statuses, the Committee first compared the waiting list mortality rates and post-transplant mortality rates of all heart candidates in each criteria, with a particular focus on better stratifying candidates currently in status 1A.[3] (**Table 1**)

[2] 2012-2015 OPTN/UNOS Strategic Plan

[3] OPTN/UNOS Descriptive Data Request: "Outcomes for Adult Candidates and Recipients by Status 1A Criteria and Diagnosis." Prepared for Heart Subcommittee Conference Call, March 12, 2013.

Table 1: All sub-criteria while waiting for those ever Status 1A Criteria A or B

Status 1A criteria	All sub-criteria while waiting	Waiting list							Transplant		
		# listed (2010-2011)	Prob. of TX			Prob. of Death			# TXed (2010-2011)	Prob. of death	
			1 month+	6 months +	12 months +	1 month+	6 months +	12 months +		6 months	12 months
A	(i)	1,169	37.2%	63.3%	72.5%	3.0%	5.1%	5.7%	1,138	8.09%	10.90%
	(ii)	58	20.7%	70.7%	*	3.5%	8.6%	*	46	21.74%	23.91%
	(iii)	452	31.9%	52.7%	60.6%	10.2%	15.5%	16.6%	344	8.14%	11.43%
	(iv)	70	24.3%	31.4%	*	35.7%	35.7%	*	25	24.00%	24.00%
B	(i)	113	38.1%	70.8%	75.2%	1.8%	6.2%	7.1%	93	6.5%	6.50%
	(ii)	228	21.5%	67.1%	76.3%	0.9%	4.8%	6.1%	262	8.02%	11.90%
	(iii)	80	21.2%	55.0%	65.0%	7.5%	11.2%	12.5%	80	8.75%	10.04%
	(iv)	28	14.3%	57.1%	*	10.7%	10.7%	*	28	14.29%	14.29%
	(v)	83	26.5%	63.9%	67.5%	1.2%	10.8%	10.8%	93	7.53%	10.90%

NOTE: Groups are not mutually exclusive. A candidate/recipient could appear in multiple sub-criteria groups.
*Rate not computed due to fewer than 10 candidates/recipients still at risk at the time point. Based on OPTN data as of February 22, 2013.
+ Time is based on first entry into sub-criteria, rather than time since listing.

Sub-criteria:
A(i)=VAD for 30 days
A(ii)=total artificial heart
A(iii)-Intra-aortic balloon pump (IABP)
A(iv)=ECMO

B(i)=MCSD with Thromboembolism
B(ii)=MCSD with infection
B(iii)=MCSD with malfunction
B(iv)=MCSD with life-threatening ventricular arrhythmia
B(v)=MCSD with other complication

The Committee reviewed data that revealed that candidates in status 1A currently have the highest waiting list mortality rates and the highest post-transplant mortality rates, and are transplanted the most often. Moreover, waiting list mortality rates among status 1A candidates vary considerably by criteria. Six month waitlist mortality among status 1A candidates varied from 4.8% in those with MCSD with infection, to 5.1% in those with VAD for 30 days, to 35.7% in those with ECMO. Status 1A candidates supported by mechanical ventilation and ECMO had the highest waiting list mortality rates, while candidates with continuous hemodynamic monitoring supported by multiple inotropes or a single high dose inotrope, VAD candidates using discretionary 30 day status 1A time, and MCSD candidates with infection exhibited the lowest waiting list mortality rates of the status 1A candidates.

The Committee also compared risk based on candidates' diagnoses at listing and at transplant within each urgency status. (**Table 2**)

Table 2: Diagnosis and Medical Urgency Status at Listing/Transplant

Diagnosis at listing/ transplant	Status at listing/ transplant	Waiting list							Transplant		
		# listed (2010-2011)	Prob. of TX			Prob. of Death			# TXed (2010-2011)	Prob. of death	
			1 month	6 months	12 months	1 month	6 months	12 months		6 months	12 months
ALL		***5761***	***17.9%***	***44.9%***	***55.4%***	***2.9%***	***6.5%***	***8.1%***	***3,757***	***7.04%***	***9.02%***
ALL		*1267*	*36.7%*	*61.9%*	*67.8%*	*6.9%*	*10.7%*	*11.4%*	*2,104*	*7.43%*	*9.78%*
Amyloidosis		17	*	*	*	*	*	*	23	8.70%	21.80%
Congenital		16	*	*	*	*	*	*	46	8.70%	8.70%
CAD		461	39.5%	68.3%	74.2%	4.6%	7.8%	8.5%	803	8.60%	11.52%
Dilated CM	**Status 1A**	639	36.2%	61.9%	68.5%	5.3%	9.3%	10.2%	1,008	6.16%	7.99%
Hypertrophic		20	15.0%	*	*	10.0%	*	*	47	6.38%	6.38%
Restrictive		14	*	*	*	*	*	*	39	0.0%	2.70%
Retransplant		73	28.8%	*	*	20.5%	*	*	46	15.59%	21.50%
Other		27	33.3%	*	*	22.2%	*	*	79	8.88%	8.88%
ALL		*2402*	*18.1%*	*50.9%*	*62.3%*	*2.3%*	*6.1%*	*7.9%*	*1,395*	*6.74%*	*8.45%*
Amyloidosis		17	*	*	*	*	*	*	12	0.0%	8.33%
Congenital		57	17.5%	54.4%	61.4%	5.3%	8.8%	10.5%	50	16.00%	18.05%
CAD		850	15.1%	51.8%	63.8%	3.2%	6.6%	8.6%	542	7.75%	8.50%
Dilated CM	**Status 1B**	1308	18.7%	49.0%	60.7%	1.3%	5.4%	7.2%	659	5.01%	7.37%
Hypertrophic		29	24.1%	*	*	0.0%	*	*	21	9.52%	9.52%
Restrictive		35	25.7%	62.9%	*	2.9%	2.9%	*	27	7.41%	7.1%
Retransplant		64	23.4%	53.1%	59.4%	7.8%	9.4%	10.9%	48	11.11%	12.96%
Other		42	31.0%	64.3%	*	4.8%	9.5%	*	30	3.33%	7.36%
ALL		*2092*	*6.4%*	*27.6%*	*39.9%*	*1.2%*	*4.4%*	*6.4%*	*258*	*5.44%*	*5.84%*
Amyloidosis		42	14.3%	45.2%	50.0%	2.4%	2.4%	2.4%	4	*	*
Congenital		118	1.7%	16.9%	33.1%	0.0%	3.4%	5.9%	8	*	*
CAD		807	5.1%	26.0%	37.3%	1.1%	4.7%	6.8%	106	3.77%	4.76%
Dilated CM	**Status 2**	816	6.4%	28.4%	41.4%	1.0%	3.9%	5.5%	93	5.41%	5.41%
Hypertrophic		67	9.0%	26.9%	52.2%	3.0%	3.0%	4.5%	12	8.33%	*
Restrictive		54	3.7%	38.9%	55.6%	0.0%	1.9%	5.6%	4	*	*
Retransplant		129	11.6%	31.8%	36.4%	3.1%	8.5%	10.1%	19	5.00%	5.00%
Other		59	15.3%	28.8%	39.0%	1.7%	5.1%	11.9%	11	*	*

*Rate not computed due to fewer than 10 candidates/recipients still at risk at the time point. Based on OPTN data as of February 22, 2013.

These data reveal that status 1A candidates have widely disparate waiting list mortality risks. Waiting list mortality and post-transplant survival rates currently vary based on medical urgency status, criteria and sub-criteria, and by diagnosis stratified by status.

The Committee also analyzed all status 1A and status 1B exception requests submitted for heart and heart-lung candidates between July 2009 and June 2011 to identify common categories of exception requests (**Figures 2 and 3**).

Figure 2: Categories for Adult Status 1A Exception Narratives (N=640)

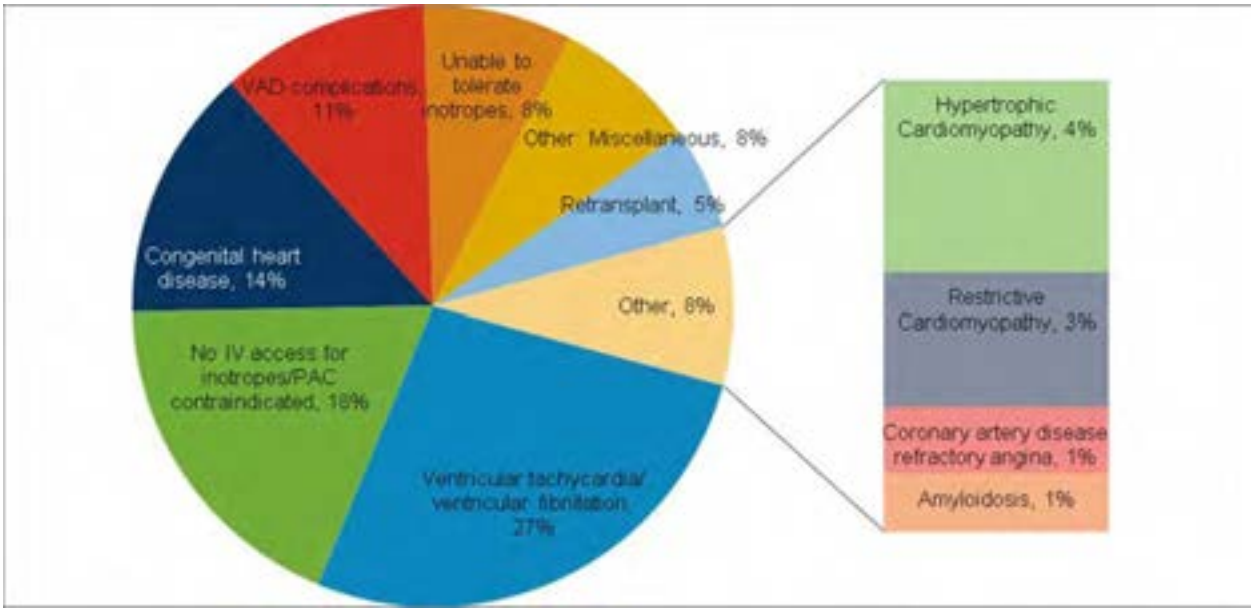
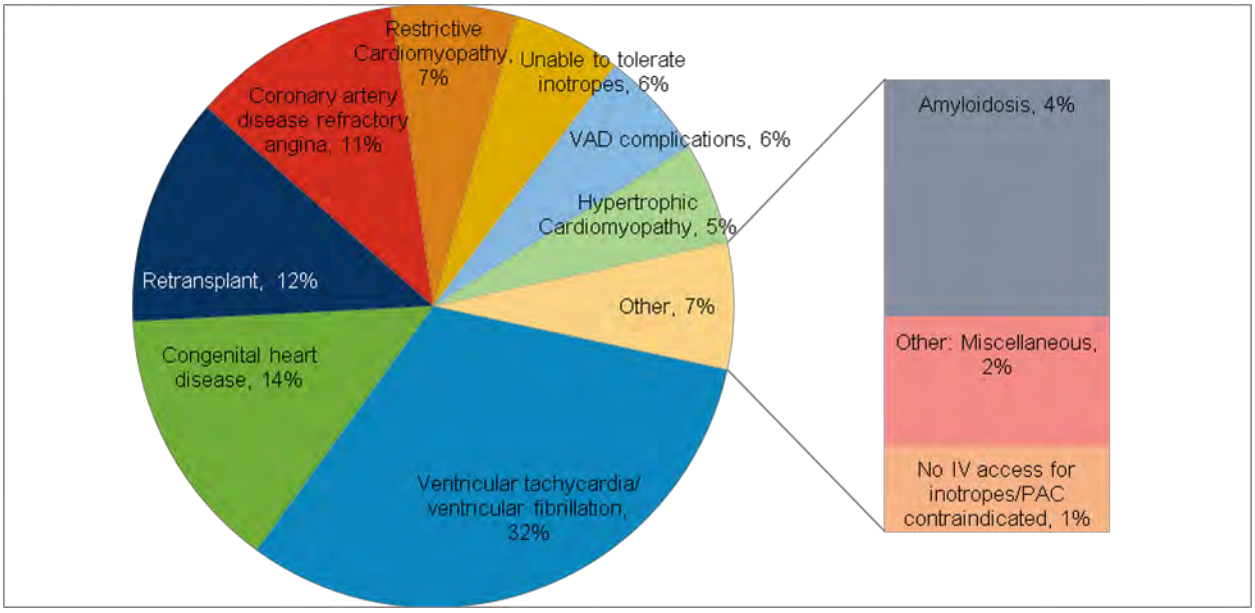


Figure 3: Categories for Adult Status 1B Exception Narratives



The three most frequently reported categories represent over half of the exception requests in both status 1A and status 1B. For status 1A, the most common rationale provided for exception requests were: 1) candidate is experiencing ventricular tachycardia or ventricular fibrillation; 2) candidate does not have intravenous access for inotropes or cannot tolerate a pulmonary artery catheter; and 3) congenital diagnosis. For status 1B, the most common rationale provided for exceptions request were: 1) candidate is experiencing ventricular tachycardia or ventricular fibrillation; 2) congenital diagnosis; or 3) candidate requires a re-transplant.

After reviewing these data, the Committee formulated a draft, or "straw man" version of the proposed statuses, to incorporate candidates that currently qualify for status 1A and 1B under policy as well as those who apply for status 1A and 1B exceptions using common supporting rationale. (**Table 3**) The straw man statuses primarily grouped candidates together by similar waiting list mortality rates, but also considered post-transplant mortality risk, as well as Committee members' experience with candidates in these groups. Within each status, candidates will be grouped together and stratified by waiting time; ECMO candidates would not necessarily receive offers before mechanically ventilated candidates, and so on.

Table 3: Proposed Straw Man Statuses as of July 24, 2014

Status	Proposed Criteria
1	i. ECMO ii. Mechanical ventilation iii. Non-dischargeable BiVAD or RVAD iv. Mechanical circulatory support with life-threatening ventricular arrhythmia
2	i. Intra-aortic balloon pump ii. Acute circulatory support device ii. Ventricular tachycardia/ventricular fibrillation, mechanical support not required iii. Mechanical circulatory support with device malfunction/mechanical failure iv. Total artificial heart v. Dischargeable BiVAD or RVAD
3	i. LVAD for up to 30 days ii. Status 1A exception iii. Multiple inotropes or single high-dose inotropes with continuous hemodynamic monitoring iv. Mechanical circulatory support with device-related complications other than infection, thromboembolism, device malfunction/mechanical failure or life-threatening ventricular arrhythmia v. Mechanical circulatory support with device infection vi. Mechanical circulatory support with thromboembolism
4	i. Diagnosis of congenital heart disease (CHD) with: a. Unrepaired/incompletely repaired complex CHD, usually with cyanosis b. Repaired CHD with two ventricles (e.g., TOF, TOGV) c. Single ventricle repaired with Fontan or modifications ii. Diagnosis of ischemic heart disease with intractable angina iii. Diagnosis of hypertrophic cardiomyopathy iv. Diagnosis of restrictive cardiomyopathy v. Stable LVAD candidates after 30 days vi. Inotropes without hemodynamic monitoring vii. Diagnosis of amyloidosis viii. Retransplant ix. Status 1B exception
5	Combined organ transplants: heart-lung; heart-liver; heart-kidney
6	All remaining active candidates
7	Inactive/not transplantable

After confirming the straw man groups, the Committee requested the SRTR perform a thoracic simulation allocation model (TSAM) to show the projected impact of the straw man statuses. The TSAM request was designed to mirror current allocation rules as closely as possible, including the intermingling of adult

candidates and pediatric candidates, in order to be verify that the modeled outcomes reflect the impact of the straw man itself, and not any other inadvertent changes to the allocation system. The results of this TSAM are described in the "How well does this proposal address the problem statement?" section below.

Development of Broader Sharing

Following a critical review of the TSAM, the Committee was satisfied that patient subgroups were more accurately stratified and began considering improvements to the geographic sharing scheme. The Committee focused on an example that highlights a significant problem in the current system: if a donor heart becomes available in northern New Jersey, a status 1B heart candidate awaiting a heart transplant within the DSA in New Jersey would receive the organ offer before a status 1A candidate awaiting a heart transplant in Zone A in New York City, just 25 miles away. The Committee believes allocating in this manner violates the Final Rule, which states that, to the extent feasible while not compromising patient health or the health of the donor organ, the OPTN's allocation policies "[s]hall not be based on the candidate's place of residence or place of listing…"

The Committee determined that broader sharing of adult hearts to the most urgent candidates first, as well as minimizing the impact of "local" sharing based on DSA, may help to ensure that the candidates most in need of transplant have access to the broadest range of available donors. The Committee debated which urgency statuses required the broadest sharing, as well as how far the first geographic allocation unit should be. Ultimately, the Committee determined that proposed statuses 1 and 2 should benefit from the broadest sharing, as these candidates are very urgent and would benefit most from exposure to more donors. The number of candidates that will qualify for proposed status 1 and status 2 is also relatively small and therefore will have a smaller impact on candidates waiting in other statuses.

The Committee also weighed the candidates' urgency against the safety of shipping organs further. If the first geographic unit were combined all the way out to Zone B (1,000 miles from the donor hospital), then outcomes might be less optimal because more urgent candidates would be transplanted with organs with longer cold ischemic time. However, the Committee also acknowledged that an organ with a longer ischemic time may be appropriate for very urgent candidates, and a preferable strategy to waiting for a local donor organ. To compromise, the Committee determined that the most urgent candidates in the DSA and Zone A should have the first opportunity, *then* Zone B urgent candidates.

The Committee also debated whether to eliminate local sharing altogether, thereby implementing Zone A (500 miles from the donor hospital) as the first geographic unit of allocation. Some members of the Committee believe that local sharing is based on arbitrary boundaries, thus violating the Final Rule. Others recognized that some reject the concept of minimizing or eliminating local sharing, asserting that people may be more willing to donate if they know their organs are going to be shared with their local community. However, this assertion has not been proven, as most people prefer their donated organs be allocated to the "more medically urgent patients regardless of where they live in the U.S."[4] and one study noted "the public tends to draw community lines at national rather than local boundaries."[5] Nevertheless, the Committee determined the best compromise is to keep local sharing as the first geographic unit of

[4] http://organdonor.gov/dtcp/nationalsurveyorgandonation.pdf

[5] M. L. Volk, G. J. W. Warren, R. R. Anspach, M. P. Couper, R. M. Merion, P. A. Ubel. "Foreigners Traveling to the U.S. for Transplantation May adversely Affect Organ Donation: A National Survey." American Journal of Transplantation: 2010; 10: 1468-1472. DOI: 10.1111/j.1600-6143.2010.03111.x

allocation, but to combine it with Zone A, so that all urgent candidates registered locally and within Zone A are grouped together, rather than sequentially.

The Committee requested an additional TSAM, building on the initial one, to model the potential impact of various broader sharing schemes. The results of this analysis are described in the "How well does this proposal address the problem statement?" section below.

Detailed Definitions for Status Criteria

The TSAMs projected the outcomes of heart candidates based on the straw man groups listed in **Table 3**, above. However, as the Committee developed the proposal, it became clear that the candidates that qualify for a status should be more specifically defined to ensure that the status comprises the patients that are truly urgent. Feedback received from the Forum on U.S. Heart Allocation Policy in November 2013[6] and a forum hosted by the American Society of Transplantation (AST) in May 2015 also emphasized that the definitions for the candidates that qualify for each status should be very clear.

The need for detailed definitions is also a lesson learned from current policy. The Committee previously attempted to clarify the "device complications" policy by publishing "Guidance Regarding Adult Heart Status 1A(b) Device-Related Complications." Indeed, many of the complications detailed in the guidance document were ultimately incorporated into the proposed policy to ensure that patients with severe device complications qualify for the most urgent statuses and to clearly show the Committee's intent regarding which complications are truly urgent. Many of the definitions included in the guidance document, and now the proposed policy, are based on data collected by the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS), as well as clinical consensus of Committee members. For other proposed definitions, the Committee continued to rely on data, clinical experience, and other external resources such as the results of clinical trials and information provided by professional societies.

Status 1

- Status 1: Veno-Arterial ECMO

The Committee determined that ECMO candidates should be in status 1 because of their high waiting list mortality rates, and because the number of candidates supported by ECMO prior to transplant is relatively low. For example, the TSAM analysis projected that under the proposed six-status system and broader sharing scheme, an average of 31 candidates were predicted to be transplanted on ECMO. Additionally, though it cannot be determined until the policy is in place, some hypothesize that rapid transplantation of ECMO-supported patients may be superior to durable MCSDs and may reduce ECMO-related complications and post-transplant mortality.

Committee members heard some reservations in the community about including ECMO in the highest urgency status, because data reveal that ECMO patients tend to have worse post-transplant outcomes than some other candidates that qualify for status 1. Additionally, some were concerned that including ECMO in the highest urgency status may inadvertently encourage transplant teams to opt for ECMO support simply to ensure their candidate qualifies for status 1. Recognizing this concern, but also recognizing that physicians would not use ECMO if it were not clinically indicated and not in the best interest of the patient, the Committee decided to keep ECMO in status 1.

Based on these concerns, however, the Committee determined the criterion for ECMO should be limited to those candidates supported by veno-arterial (VA) ECMO. It agreed that veno-venous (VV) ECMO is

[6] J. A. Kobashigawa, M. Johnson, J. Rogers, J. D. Vega, M. Colvin-Adams, L. Edwards, D. Meyer, M. Luu, N. Reinsmoen, A. I. Dipchand, D. Feldman, R. Kormos, D. Mancini11 and S. Webber on behalf of the forum participants. Meeting Report: Report from a Forum on US Heart Allocation Policy. American Journal of Transplantation 2015; 15: 55–63. doi: 10.1111/ajt.13033.

the ultimate form of respiratory failure and is not generally an appropriate indication for heart transplant. The Committee will closely evaluate the effect of allowing VA ECMO candidates to qualify for status 1A.

- Status 1: Continuous Mechanical Ventilation

The Committee debated whether continuous mechanical ventilation should remain in policy. Committee members noted that continuous mechanical ventilation is not usually an indication for heart transplant, and, like ECMO, these candidates may have a higher post-transplant mortality. The Committee reviewed data regarding the number of transplant recipients that were registered as status 1A under the continuous mechanical ventilation criterion at the time of their transplant. Between 2012 and 2014, over 420 patients used continuous mechanical ventilation as status 1A criteria at least once, and about 20 patients per year received transplants while registered as status 1A with continuous mechanical ventilation as the justification.[7] Based on the relatively high number of candidates using this status each year, the Committee determined it is not appropriate to remove continuous mechanical ventilation from policy. Additionally, like ECMO, the number of patients using this justification for status 1 is likely to be small. The Committee proposes requiring that the candidate also have endotracheal intubation to clarify that this status is intended to capture candidates that are on continuous mechanical ventilation, not Bilevel Positive Airway Pressure (BiPAP) or Continuous Positive Airway Pressure (CPAP).

- Status 1: Non-Dischargeable VADs

This status is intended to apply to candidates supported with a VAD that is not approved for use outside the hospital. The Committee clarified that "non-dischargeable" is intended to describe only the device, and not the patient. Therefore, if a candidate is supported by an LVAD that is approved for discharge from the hospital, but the candidate cannot be discharged due to their course of treatment for an unrelated condition, that candidate does not qualify for this criterion. UNOS will maintain a list of devices that qualify for this category in UNet^{SM}, and the Committee will review and update this list annually to ensure that it is up-to-date. When a transplant program registers a candidate under this criterion, the transplant program will indicate which device is supporting the candidate. The current list of non-dischargeable devices is included in **Appendix A**.

- Status 1: MCSD with Life Threatening Ventricular Arrhythmias

Upon reviewing all the device complications reported to the OPTN, the Committee determined that the waiting list mortality rate for candidates supported by an MCSD and experiencing a life threatening ventricular arrhythmias was worse than for candidates experiencing any other device complication. Therefore, the Committee determined these candidates should be included in status 1. Because this is a common complication, the Committee agreed to make the qualifying criteria for this criterion strict to ensure that only the most urgent patients qualify, and adopted the definition from the Criterion (b) Guidance document.

Status 2

- Status 2: Total Artificial Heart (TAH)

This status is intended to apply to all candidates supported with a TAH, regardless of whether they are admitted to the hospital. Though data revealed that candidates implanted with a TAH have similar waiting list mortality rates to other candidates in status 2, there is still debate regarding whether all TAH candidates should be grouped together. Current OPTN data does not distinguish between candidates that are admitted to the hospital and those that are not. Though there is an assumption that outpatient candidates supported by TAH are more stable than some other candidate groups in status 2, the

[7] Based on OPTN data presented on October 22, 2015.

Committee also recognized that outpatient or not, TAH can be a challenging support technology. Additionally, regardless of hospital admission, TAH failure tends to be extremely urgent due to lack of backup circulatory support from the native heart. The Committee also recognized that it is the candidate's disease process, more than the therapy, that should determine the status for which a candidate qualifies, and for TAH candidates, their disease process is most similar to candidates supported by a biventricular assist device (BiVAD).

The Committee also noted that some transplant programs perform a ventriculectomy for a patient and then implant a BiVAD. The Committee agreed that candidates supported in this manner are more similar to candidates with TAH, and therefore the definition for TAH was expanded to include these candidates.

- Status 2: Dischargeable Right Ventricular Assist Device (RVAD), BiVAD, or Single Ventricle Patients with LVAD

Candidates supported by RVADs or BiVADs that are approved for discharge from the hospital qualify for this criterion. UNOS will maintain a list of qualifying devices in UNet^{SM} which will be reviewed annually by the Committee. The current list of dischargeable devices is included in **Appendix A**. Additionally, candidates with single ventricle congenital heart disease anatomy supported by an LVAD qualify for status 2 under this criterion. The Committee agreed that these candidates are distinct from candidates with two ventricles supported by a dischargeable LVAD, and therefore are more appropriately grouped with status 2 candidates.

- Status 2: MCSD with Malfunction

Candidates supported by a MCSD that is experiencing a malfunction are intended to qualify under this criterion. The Committee adopted the definition for device malfunction from the Criterion (b) Guidance Document, which was largely informed by the INTERMACS definition of device malfunction. Some members of the community inquired whether this criterion is intended to capture patients experiencing pump thrombosis related to their device. The Committee clarified pump thrombosis is *not* meant to be included in this category, as there is a status 3 criterion specifically for MCSD with pump thrombosis. This status is meant to capture candidates whose device has malfunctioned to the point that the entire device requires replacement.

- Status 2: Acute Circulatory Support (ACS) Device

The Committee reviewed data to support placing ACS candidates in status 2.[8] The cohort used in the TSAMs includes candidates registered for a heart transplant between mid-2009 to mid-2011. This cohort pre-dates the rapid growth of heart candidates supported by ACS, so the Committee reviewed data regarding waiting list and post-transplant outcomes for candidates supported by ACS between 2011 and 2013. During this period, about 11,000 heart-alone candidates were registered for transplant, and approximately 4% were registered with ACS at listing, most commonly with a balloon pump.

For all ACS candidates combined, the death/too sick rate was 31 per 100 patient years, compared with 34 per 100 patient years for all status 1A candidates and 21 per 100 patient years for candidates on inotropes. At time of transplant, 6% of candidates were supported by an ACS device, and the vast majority of those candidates were supported by a balloon pump alone. The two-year post-transplant survival rates for candidates transplanted while supported by an ACS was 84%, midway between BiVADs (82%) and LVADs (86%).

When the Committee initially designed the straw man, it placed candidates with balloon pumps in status 2 based on supporting data and clinical experience, because those candidates are not as urgent as

[8] OPTN Data presented on July 24, 2014.

candidates supported by ECMO. The Committee was similarly wary of assigning ACS candidates to status 1, because the death rate for some ACS devices is closer to those candidates with balloon pump, and they do not appear to be as urgent as those candidates on ECMO. Additionally, the Committee does not want to create an inadvertent incentive for transplant teams to treat with ACS in order to place their candidates in status 1.

To further avoid creating an inadvertent incentive to treat with ACS, the Committee proposes a requirement that the candidate be treated with ACS specifically for cardiogenic shock, and created a hemodynamic threshold of showing the candidate had a cardiac index of less than or equal to 2.2 L/min/m^2 prior to ACS implantation. This cardiac index value was adopted from previous studies related to cardiogenic shock.[9] To be consistent throughout policy, each time the Committee proposed a hemodynamic requirement in addition to therapy, the Committee included the proposed threshold of a cardiac index less than or equal to 2.2 L/min/m^2.

UNOS will maintain a list of qualifying ACS devices in UNet^{SM} which will be reviewed annually by the Committee. The current list of ACS devices is included in **Appendix A**.

- Status 2: Intra-aortic balloon pump (IABP)

The Committee discussed whether candidates supported by IABP should be in status 2, and whether they should be in the same status as those candidates treated with TAH. Though the waiting list mortality and post-transplant survival rates for candidates supported by IABP are worse than for those candidates supported by TAH, clinical practice led Committee members to believe that these two candidate groups are reasonable in the same status, and that IABP candidates are comparable to candidates supported by ACS devices. Like the ACS device patients, for this status the Committee also proposes a requirement that the candidate be treated with IABP specifically for cardiogenic shock, and created a hemodynamic threshold of showing the candidate had a cardiac index of less than or equal to 2.2 L/min/m^2 prior to ACS implantation.

- Status 2: Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF)

This status was informed by the large number of transplant programs that requested status 1A exceptions for candidates experiencing recurrent or sustained VT or VF. This criterion does not require the candidate to be supported by an MCSD, however the rest of the definition was adapted from the Criterion (b) Guidance Document and mirrors the requirements for status 1: MCSD with life-threatening ventricular arrhythmia.

Status 3

- Status 3: Dischargeable LVAD for 30 Days

Current policy permits stable candidates supported by a VAD to be registered as status 1A for 30 days at the transplant program's discretion. The Committee discussed whether the 30 day optional period should continue as a policy at all.[10] Those who oppose the discretionary 30 day time cite studies that show that stable LVAD patients are at a much lower risk of experiencing adverse events while waiting for transplant,

[9] Hochman, Judith S., Lynn A. Sleeper, John G. Webb, Timothy A. Sanborn, Harvey D. White, J. David Talley, Christopher E. Buller et al. "Early revascularization in acute myocardial infarction complicated by cardiogenic shock." New England Journal of Medicine 341, no. 9 (1999): 625-634. DOI: 10.1056/NEJM199908263410901

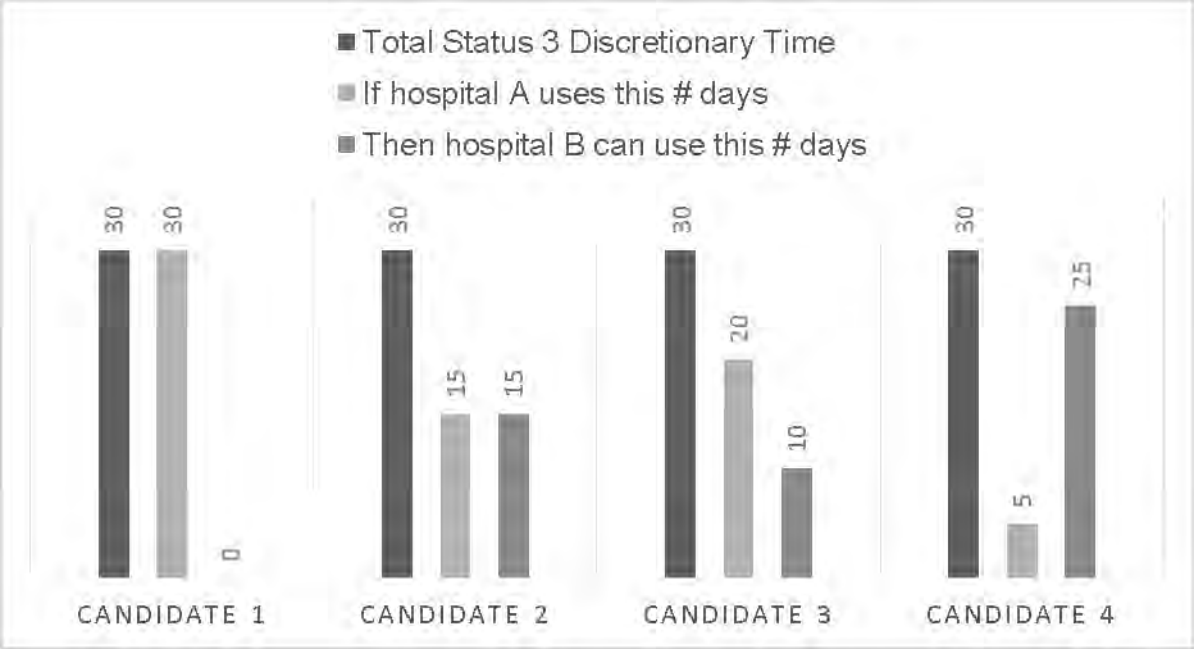
[10] D. M. Meyer; J. G. Rogers; L. B. Edwards; E. R. Callahan; S. A. Webber; M. R. Johnson; J. D. Vega; M. J. Zucker; J. C. Cleveland Jr., The Future Direction of the Adult Heart Allocation System in the United States. American Journal of Transplantation. 2015;15(1):44-54.

and are therefore not nearly as urgent as other candidates in status 3.[11,12] Those who supported the optional 30 day period believe the TSAM analysis reveals that the candidates using the LVAD for 30 days discretionary time have lower waiting list mortality rates than others in status 3 as a direct result of an intentional compromise that provides candidates with a priority for a limited time without forcing them to risk developing a device complication in order to move up in urgency.

Ultimately, the Committee determined that the discretionary LVAD for 30 days policy should continue. It is an acceptable compromise that provides candidates supported by an LVAD with an opportunity for transplant while stable, which likely increases the opportunity for successful transplantation.

The Committee also clarified that candidates that are supported by a dischargeable LVAD and registered at more than one hospital nevertheless only receive 30 days of discretionary time total. (**Figure 4**)

Figure 4: Examples of Discretionary 30 Day LVAD Time for Candidates Registered at Multiple Hospitals



In Figure 4, Hospital A registered Candidate 1 for 30 days under the discretionary status 3 criterion, and therefore Hospital B may not register Candidate 1 as status 3 under this criterion. Hospital A and B simultaneously registered Candidate 2 as status 3, so the candidate can only be registered for 15 days of status 3 time at each of the hospitals. Hospital A registered Candidate 4 as status 3 for 20 days, so Hospital B can only register Candidate 3 as status 3 for 10 more days. Finally, Hospital A only registered Candidate 4 as status 3 for 5 days under this criterion, so Hospital B can register Candidate 4 for up to 25 days of discretionary status 3 time. The Committee believes this is the fairest way of permitting candidates simultaneously registered at multiple hospitals to have access to status 3, while not disadvantaging other candidates that are not capable of multiple listing. If a candidate's device is

[11] Dardas T, Mokadam NA, Pagani F, Aaronson K, Levy WC. Transplant registrants with implanted left ventricular assist devices have insufficient risk to justify elective Organ Procurement and Transplantation Network status 1A time. J Am Coll Cardiol 2012; 60: 36–43.
[12] Pinney SP. Timing isn't everything: Donor heart allocation in the present LVAD era. J Am Coll Cardiol 2012; 60: 52–53.

replaced, then the candidate is eligible for another 30 day discretionary period, and any remaining 30 day time from the previous device does not carry over to the new device.

- Status 3: Multiple Inotropes or a Single High Dose Inotrope and Hemodynamic Monitoring

This status was largely informed by the requirements in current policy. To avoid inadvertently creating an incentive to administer inotropes in order to register a candidate as status 3, the Committee adopted the same hemodynamic threshold requiring that the candidate had a cardiac index of less than or equal to 2.2 L/min/m^2 prior to or during administration of the inotropes.

The Committee debated whether the hemodynamic monitoring should be more stringent, to only allow monitoring via a pulmonary artery (PA) catheter. Committee members in support of this requirement noted that requiring this invasive technique would ensure that less urgent candidates qualify for this status by being administered inotropes but not being exposed to the risks associated with invasive hemodynamic monitoring. Others felt the requirement for invasive hemodynamic monitoring via PA catheter was too prescriptive, particularly as other non-invasive techniques for monitoring hemodynamics are being developed. Ultimately, the Committee compromised by agreeing that candidates must either have a pulmonary artery catheter in place, or be monitored on a daily basis by an instrument that measures cardiac output *and* left ventricular filling pressures.

Though current policy permits candidates to qualify for status 1A using similar criteria, the list of qualifying inotropes was not previously included in the policy language. The Committee decided to include a list in policy to make the policy more transparent, and because this list is not likely to change frequently.

- Status 3: MCSD with Hemolysis

The Committee adopted the definition for MCSD with hemolysis from the Criterion (b) Guidance Document. This criterion is intended to apply to candidates whose devices are functioning normally, but who are experiencing hemolysis. When developing these criteria for the Criterion (b) document, qualifying elevated lactate dehydrogenase and plasma-free hemoglobin values were informed by clinical trials.[13] To qualify for this status under this criterion, the candidate must also fail treatment with at least one intravenous therapy for hemolysis.

- Status 3: MCSD with Pump Thrombosis

The Committee also adopted this definition from the Criterion (b) Guidance Document, but with two notable changes. First, the Criterion (b) Guidance Document included hemolysis as evidence of pump thrombosis. However, the Committee removed this reference in the proposed policy for MCSD with pump thrombosis because MCSD with hemolysis is a separate criterion within the same status. Additionally, if the evidence of pump thrombosis is a transient ischemic attack, stroke, or peripheral thromboembolic event, the Committee removed the requirement currently in the Criterion (b) Guidance Document that such an event result in "permanent neurological deficits associated with a new defect on an imaging study." The Committee believes it is appropriate to permit a transient ischemic attack to serve as evidence of pump thrombosis, and the requirement for *permanent* neurological deficits contradicts that requirement.

- Status 3: MCSD with Right Heart Failure

This criterion was adapted from the Criterion (b) Guidance Document but has been modified. This criterion was developed by reviewing data from previous trials, which defined right failure as requiring at

[13] Shah P, Mehta VM, Cowger JA, Aaronson KD, Pagani FD. Research Correspondence: Diagnosis of Hemolysis and Device Thrombosis with Lactate Dehydrogenase during Left Ventricular Assist Device Support. JHLT. J Heart Lung Transplant. 2014 Jan;33(1):102-4. doi: 10.1016/j.healun.2013.07.013.

least two weeks of intravenous inotropes to support right heart function or support of an RVAD.[14] However, in the proposed policy the Committee removed RVAD support as evidence of right heart failure because placement of an RVAD would qualify the candidate for status 2. The Committee agreed it is appropriate to require physiologic evidence of clinical right heart failure based upon elevation of the central venous pressure, and need for intravenous inotropes. Inhaled pulmonary vasodilators were not included in the trials supporting this criterion, but the Committee agreed it is reasonable to include them. The Committee also noted it is important to permit intravenous pulmonary vasodilator therapy to qualify for this criterion, as it is meant to distinguish these patients from those that are on oral therapies.

- Status 3: MCSD with Device Infection

The Committee largely adopted the proposed policy for this criterion from the Criterion (b) Guidance Document, but added more clarity based upon disparities that currently exist regarding the infections that qualify a candidate for this status. First, the Committee proposed deleting "warmth" along the driveline as an infection indicator. Additionally, the Committee proposes adding a new category to capture patients with recurrent bacteremia.

The Committee also carried forward the language in current policy, stating the candidate "is experiencing" an infection. This language is intended to capture patients with a current infection that meets the requirements, but not those candidates whose infections have resolved and are not experiencing the conditions detailed in policy.

- Status 3: MCSD with Mucosal Bleeding

The definition for this criterion was adapted from the Criterion (b) Guidance Document, but was changed to capture candidates with an instance of mucosal bleeding, and candidates with recurrent, unresolved mucosal bleeding. The original intent was to allow candidates to qualify for this criterion the second time they are admitted to the hospital for bleeding, and to not require them to have to undergo repeated invasive testing. However, the Committee noted there should be a maximum timeframe allowed between these hospital visits to be considered recurrent, and decided based on clinical consensus that six months is an appropriate amount of time to allow between hospitalizations. This criterion is intended to capture candidates who are experiencing active bleeding that is pathophysiologically related to their VAD therapy, rather than candidates that cannot be anticoagulated.

- Status 3: MCSD with Aortic Insufficiency (AI)

The definition for this criterion was also adapted from the Criterion (b) Guidance Document, but was changed slightly to clarify that the hemodynamic symptoms are not due to pump dysfunction. The Committee discussed whether 70 mmHg is too low of a mean arterial pressure (MAP) for this criterion. Committee members agreed that the severity of aortic insufficiency may be influenced by systemic blood pressure and that determination of severity should be made while the patient is not hypertensive. The Committee was also wary of making the MAP too low because it does not want to overload the regional review boards with exception requests. Ultimately, the Committee agreed that 80 mmHg is a good compromise for the MAP to qualify for this criterion. The Committee agreed the wedge pressure is an

[14] Kormos RL, Teuteberg JJ, Pagani FD, et al. Right ventricular failure in patients with HeartMate II continuous flow left ventricular assist device: Incidence, risk factors, and effect on outcomes. J Thorac Cardiovasc Surg 2010; 139:1316-24.

important qualifying sub-criterion for demonstrating AI because it proves there is a hemodynamic consequence resulting from the AI.

Status 4

- Status 4: Dischargeable LVAD without Discretionary 30 Days

This proposed policy mirrors current policy, and is intended to apply to all candidates supported by a dischargeable LVAD that are not using the discretionary 30 days of status 3 time. This includes candidates that have already used all of their discretionary 30 days and patients who have discretionary status 3 time remaining but are not currently using it.

- Status 4: Inotropes without Hemodynamic Monitoring

This proposed policy also mirrors current policy, with one significant change. The Committee proposes implementing the same hemodynamic threshold of a cardiac index of less than or equal to 2.2 L/min/m^2 to ensure that candidates are not being treated with inotropes in order to qualify for status 4 without physiological indication of the need for inotropes.

- Status 4: Congenital Heart Disease

The Committee determined that the adult heart policy should be consistent with pediatric heart policy in defining significant congenital heart diseases that qualify a candidate for status 4. The list of qualifying congenital heart disease diagnoses approved by the Board of Directors for pediatric heart candidates in June 2014 was based on the Pediatric Heart Transplant Study (PHTS) and is included in **Appendix B**.

- Status 4: Ischemic Heart Disease with Intractable Angina

The proposed definition for ischemic heart disease with intractable angina is intended to distinguish candidates experiencing angina from those experiencing non-cardiac chest pain. The Committee proposes requiring the myocardial ischemia to be demonstrated by imaging to introduce objective evidence of the ischemia. For further objectivity and to ensure that only the most urgent candidates qualify for status 4 under this criterion, the Committee proposes requiring evidence of Canadian Cardiovascular Society Grade IV angina pectoris.

- Status 4: Amyloidosis, Hypertrophic Cardiomyopathy (HCM), or Restrictive Cardiomyopathy (RCM)

The Committee discussed whether a diagnosis of amyloidosis, HCM, or RCM is all that should be required to qualify for status 4. The Committee initially expressed reservations about creating additional criteria to qualify for this criterion, as data used to support this status were based on the candidates' diagnosis without any additional consideration. However, the Committee feared that only requiring the diagnosis might result in transplant programs listing non-urgent patients and status 4 may become saturated by candidates with very disparate waiting list urgencies. Adhering to its intent to ensure that only the most urgent candidates qualify for each status, the Committee determined that a diagnosis is not enough to qualify for status 4 under this criterion. Therefore, in addition to being diagnosed with one of these diseases, the Committee proposes that the candidate must also exhibit at least one symptom or physiological abnormality associated with advanced disease.

- Status 4: Re-transplant

Similarly to the amyloidosis, HCM, and RCM criterion, the Committee debated whether to propose requirements in excess of the transplant program's determination that the candidate requires a heart re-transplant. To be consistent with the other proposed policies, the Committee again proposes requiring

additional objective evidence of the need for re-transplant, including ISHLT CAV_2 or CAV_3 coronary anatomy, or NYHA Class III-IV heart failure symptoms.

Status 5

- Status 5: Combined Organ Transplants

This status is reserved for heart transplant candidates that are registered on the waiting list at the same transplant hospital for another organ. If a heart candidate also requires another organ, and qualifies for a more urgent status, the candidate should be registered at that status instead. This criterion is intended to capture those candidates that do not otherwise qualify for a more urgent heart status but are registered for a second organ.

The Committee acknowledged that data show that multi-organ candidates have worse post-transplant survival than candidates in status 6. However, the TSAM projected that these candidates have waiting list mortality rates and waiting times more comparable to status 4 candidates than status 6 candidates, so it is more equitable to permit these candidates to qualify at a higher status.

Status 6

- Status 6: Candidates Suitable for Heart Transplant

Lastly, this status is intended to capture all candidates that are deemed suitable for transplant but do not qualify for a more urgent status. This status is most comparable to status 2 in current policy.

Additional Policy Clarifications

The Committee proposes additional policy clarifications that are necessary due to the change in status criteria and definitions. First, the Committee proposes changes to Policy 6.5.F: Allocation of Heart Lungs, to clarify that when allocating a heart-lung block from the lung or heart-lung match run, the OPO does not need to first offer the heart to all eligible heart-alone candidates in all zones. Instead, if the OPO generates a lung or heart-lung match, the OPO can offer the heart-lung to the heart-lung candidate after offering the heart to all eligible status 1 or status 2 candidates within the DSA, Zone A and Zone B. The Committee proposes equating proposed status 1 and status 2 candidates to current status 1A candidates for the purposes of this section of policy. This clarification closely mirrors the guidance the Committee previously developed.[15]

The Committee also proposes a minor clarification to Policy 6.3.B: Exceptions to Allocation for Sensitized Patients. Current policy permits an OPO to allocate a heart out of sequence within a DSA to a sensitized candidate if the OPO and all transplant programs within the DSA agree. The proposed policy also permits this, but adds a restriction that the heart may be allocated out of sequence within the DSA but only within a status. The Committee believes this restriction is necessary because with broader sharing, an out-of-sequence allocation within a DSA would have a larger impact on candidates in Zone A and Zone B than it would in the current system.

How well does this proposal address the problem statement?

The Committee requested two TSAM analyses as it developed this proposal in order to simulate the impact of the proposed changes. The first simulation analysis demonstrated the projected impact of stratifying candidates based on a 6-tiered urgency system, rather than the current three tiers. The allocation rules for the first analysis were otherwise intended to mimic current allocation policy as closely as possible, so the first analysis does not share donated organs more broadly than the current allocation

[15] "Guidance to Organ Procurement Organizations for Allocation of Heart-Lung Blocks." https://optn.transplant.hrsa.gov/media/1139/heart_lung_allocation_guidance.pdf (last visited January 15, 2016)

system. The second analysis was based on the proposed 6 urgency statuses, but also incorporated broader sharing schemes into the allocation rules.

For each analysis, the SRTR performed ten runs of the TSAM using a real cohort of candidates and donors between 2009 and 2011. Each simulation run uses the true list of donors and candidates from the cohort, but changes the order in which the donors appear, thus changing the order of candidates to whom offers are made. The simulations are run ten times with these different orderings to account for a range of variability. Thus, simulation results show a range of outcomes across the ten runs, as well as a point estimate of the average across the ten runs (ranges do not indicate confidence limits). The first TSAM analysis, which tested the projected impact of the 6-tiered urgency system with the current geographic sharing rules, showed reductions in overall waiting list mortality rates, increases in transplant rates among the most urgent patients, and similar post-transplant mortality overall as compared to the current system.[16] Results of the first analysis are included in the figures in this proposal as "6 StatGrps" and will be referenced throughout this section as "6 urgency statuses."

The second TSAM analysis used the same cohort and builds on the results of the first analysis of the 6 urgency statuses. (**Exhibit A**) The Committee requested the SRTR model four different broader sharing schemes, and the results are included in the second analysis report.[17] The Committee ultimately decided to design the proposal based on the results shown for the modeling scheme shown in **Figure 5** below. The proposed scheme is demonstrated in the following figures as "6 GrpShare" and will be referenced throughout this section as "6 urgency statues with broader sharing."[18]

[16] Colvin M, Pyke J, Skeans M, Wang X, Zeglin J. Final Analysis: Data Request from the Heart Subcommittee of the Thoracic Organ Transplantation Committee. Data Request ID: HR2014_05. March 23, 2015.

[17] Colvin M, Bolch C, Pyke J, Skeans M, Wang X, Zeglin J. Analysis Report: Data Request from the Heart Subcommittee of the OPTN Thoracic Organ Transplantation Committee. Data Request ID: HR2015_01. October 26, 2015.

[18] The data displayed in these figures as under the heading of "6 GrpShare" corresponds with the "Sh 1/2A" data in the second TSAM report.

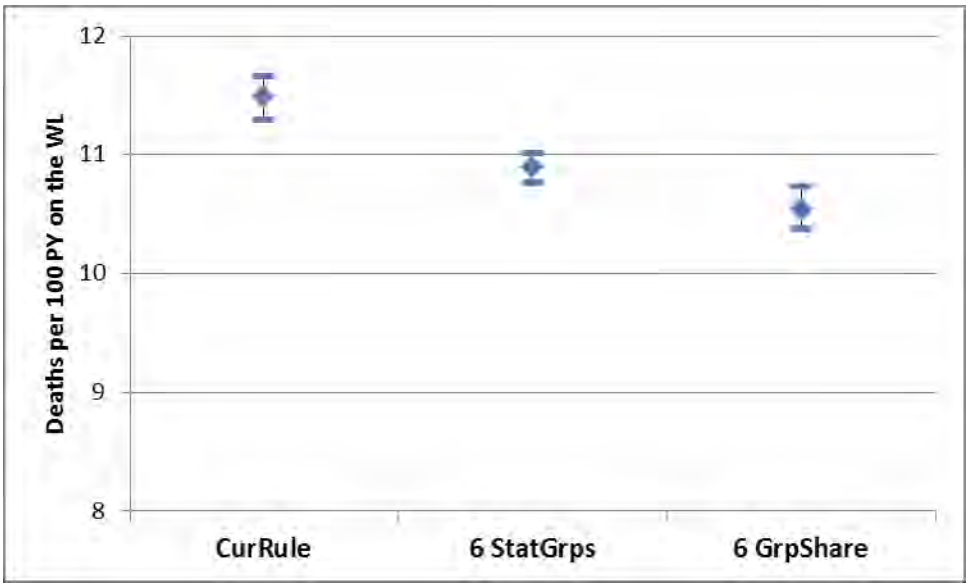
Figure 5: 6 Urgency Statuses Plus Broader Sharing

New candidate status	Location
Status 1 adult + Status 1A pediatric	DSA + Zone A
Status 1 adult + Status 1A pediatric	Zone B
Status 2 adult	DSA + Zone A
Status 2 adult	Zone B
Status 3 adult + Status 1B pediatric	DSA
Status 4 adult	DSA
Status 3 adult + Status 1B pediatric	Zone A
Status 5 adult	DSA
Status 3 adult + Status 1B pediatric	Zone B
Status 6 adult + Status 2 pediatric	DSA
Status 1 adult + Status 1A pediatric	Zone C
Status 2 adult	Zone C
Status 3 adult + Status 1B pediatric	Zone C
Status 4 adult	Zone A
Status 5 adult	Zone A
Status 6 adult + Status 2 pediatric	Zone A
Status 1 adult + Status 1A pediatric	Zone D
Status 2 adult	Zone D
Status 3 adult + Status 1B pediatric	Zone D
Status 4 adult	Zone B
Status 5 adult	Zone B
Status 6 adult + Status 2 pediatric	Zone B
Status 1 adult + Status 1A pediatric	Zone E
Status 2 adult	Zone E
Status 3 adult + Status 1B pediatric	Zone E
Status 4 adult	Zone C
Status 5 adult	Zone C
Status 6 adult + Status 2 pediatric	Zone C
Status 4 adult	Zone D
Status 5 adult	Zone D
Status 6 adult + Status 2 pediatric	Zone D
Status 4 adult	Zone E
Status 5 adult	Zone E
Status 6 adult + Status 2 pediatric	Zone E

The second TSAM analysis examining the use of the 6 urgency statuses with broader sharing rules indicated that waiting list mortality rates appeared to decrease under the broader sharing rules as compared to current rules. See **Figure 6:** The overall waiting list mortality rates in the proposed system

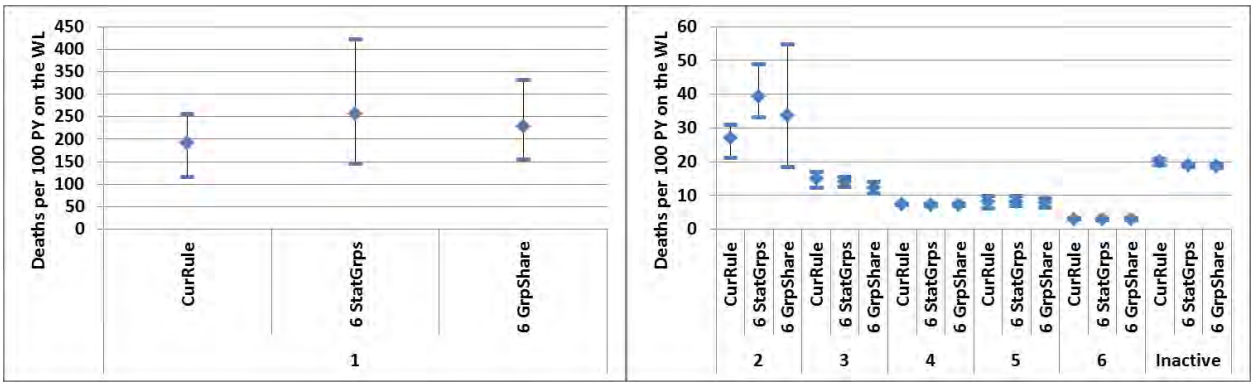
are likely to decrease because organs will be allocated to sicker patients more quickly. Candidates that are less urgent might not be transplanted as quickly, but they are also less likely to die while waiting.

Figure 6: Overall Waitlist Mortality Rates by Simulation



The waiting list mortality rates for candidates registered as inactive also decrease in the proposed system, because more urgent candidates are projected to be transplanted before reaching a state in which they are too ill for transplant and transferring to "inactive" status. (**Figure 7**). This reduces the number of waiting list deaths and decreases overall waiting list mortality rates.

Figure 7: Waitlist Mortality Rates by Simulation and New Status Groups, Adult Candidates

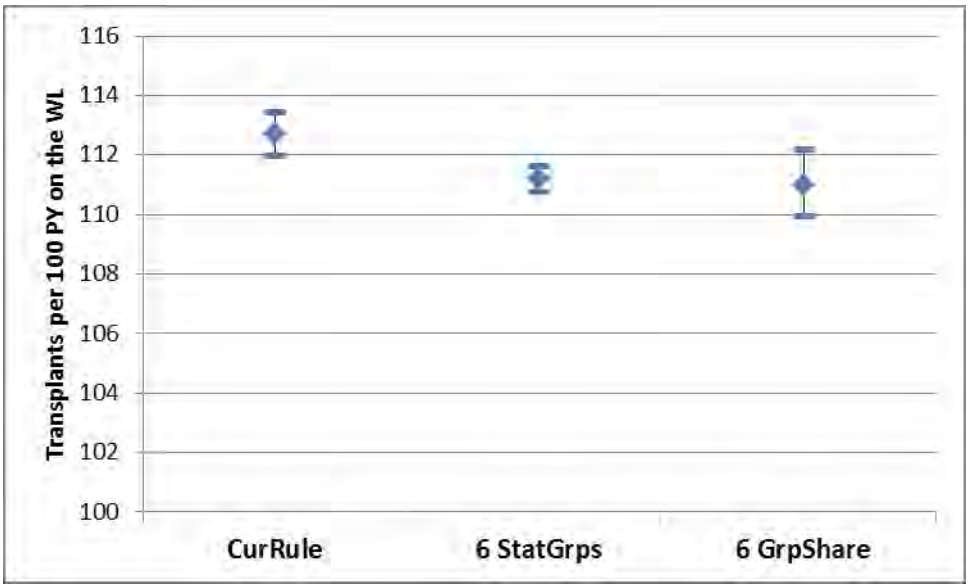


To combat the potential increase in waiting list mortality for the most urgent patients, the Committee determined that it should allow these candidates access to a broader geographic range of donors. Because of this, the waiting list mortality rates for statuses 1, 2, and 3 noticeably decrease in the 6 urgency statuses with broader sharing scheme compared to the 6 urgency statuses. Though status 1 candidates exhibit the highest projected waiting list mortality rates, the rates are comparable to the rates in the current system. The rates are also based on a very small number of deaths, thus appearing high even though the actual occurrence of death in the model ranges between 4 and 9 status 1 candidates with broader sharing, compared to 11 to 19 deaths under current rules and 7 to 18 deaths with six urgency statuses without broader sharing. Thus, while the rate estimate is higher in the proposed system, the number of status 1 and 2 candidates predicted to die while waiting is lower than the current system. Additionally, the waiting list mortality rate for status 3 declines in the 6 urgency statuses with broader

sharing scheme, reflecting much larger group of patients than those that would qualify for proposed statuses 1 and 2.

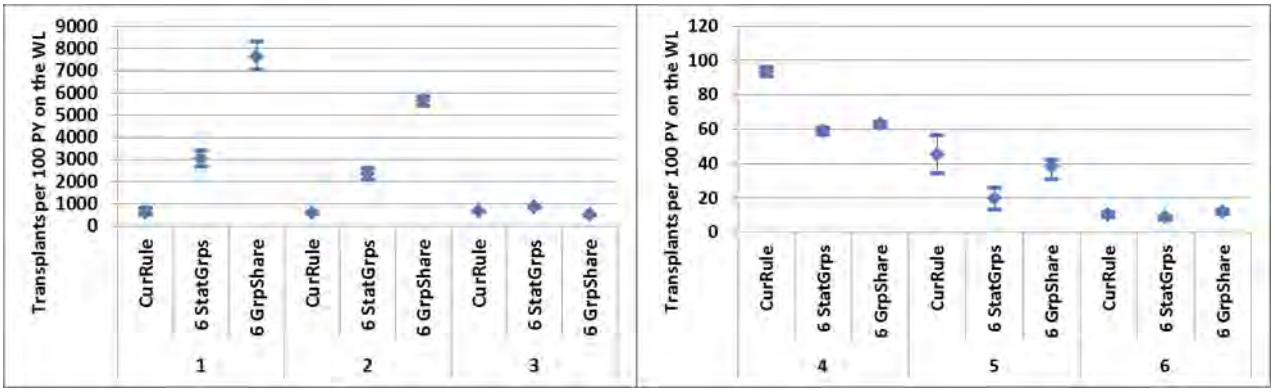
Overall transplant rates by simulation appeared to be slightly lower in the proposed sharing schemes than in the current rules. See **Figure 8**. However, the ranges of some sharing rules overlapped with the ranges exhibited in the current rules simulation. It is also important to remember that the bars in this graph represent the minimum and maximum results of the ten simulated runs; they are not the 95% confidence limits.

Figure 8: Overall Transplant Rates by Simulation



Importantly, the proposed system is intended to ensure that the most urgent candidates are transplanted more quickly, and the TSAM analysis of the proposed geographic sharing schemes demonstrate this goal. (**Figure 9**) Note that the upper y-axis limit is 9000 on the left panel and 120 on the right panel.

Figure 9: Transplant Rates by Simulation and New Status Groups, Adult Candidates

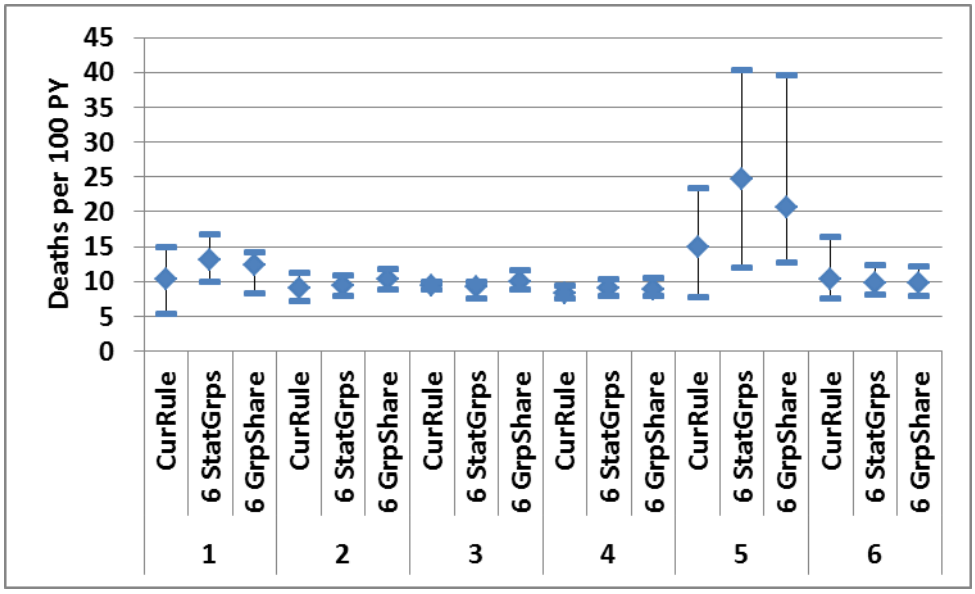


The Committee designed the proposed system to ensure that candidates most in need of transplant are prioritized in allocation. Broader sharing is projected to increase the transplant rates in status 1 and 2 because there are increased transplant counts and decreased waiting times for these patients, which contribute to higher rates. Under the current rules simulation, there are 51 transplants in status 1, but when applying broader sharing, the transplant counts increase nearly four-fold to 191. Status 1 transplant rates increase even more, from 615 transplants per 100 years on the waitlist under current rules, to 3,044

with six statuses, to 7,627 with six statuses plus broader sharing. The same pattern occurs in status 2. Increased transplant rates for these statuses under broader sharing are expected; the more priority given to statuses 1 and 2, the more one would expect to see the patients in these statuses receiving transplants. Transplant rates for status 3 candidates appear similar when comparing the current sharing rules to the proposed 6 urgency statuses with broader sharing. Status 4 candidates exhibit lower transplant rates for the two simulations involving the proposed statuses compared to the simulation based on current rules, but this was also expected. Importantly, there is not a marked increase in death counts, meaning the candidates wait longer, but are not dying more frequently.

In the proposed system, within each status the post-transplant mortality rates are projected to remain comparable to those rates in the current system. (**Figure 10**) One-year post-transplant mortality rates show a similar pattern.

Figure 10: Two-Year Post-Transplant Mortality Rates by Simulation and Tier, Adult Recipients



The post-transplant mortality rates for the simulations based on broader sharing trend slightly higher than the simulation based on current rules. The Committee expressed concern about unintentionally increasing post-transplant mortality rates as a result of increasing transplants in the most urgent patients. While status 1 post-transplant mortality rates appear to increase slightly, the modeling may not as accurately predict whether those candidates would do better if they were transplanted more quickly, as the post-transplant mortality models are based on outcomes in recipients transplanted under current rules, where all status 1A candidates receive the same priority. It is possible that these candidates may begin to have improved post-transplant mortality due to shorter wait times at the highest urgency. These are candidates that may have otherwise died while waiting for transplant.

The death rates in status 1 are higher than in status 2, but are also based on a smaller death count. This result is expected because the number of transplants for status 1 candidates is likely to increase, and the modeling appears to show the post-transplant death rate rising in concert with the increased rate of transplants for candidates in the same status. The Committee agreed that though status 1 candidates may experience slightly higher post-transplant mortality rates, prioritizing them is a clinically acceptable compromise, particularly when delaying transplantation would likely result in death on the waiting list.

The Committee's decision to propose this particular broader sharing scheme, rather than the similar scheme (described in the TSAM analysis as Share 1/2B), centered largely on the distinction between the

way in which status 3 and status 4 candidates are impacted by broader sharing. Under the proposed scheme, local status 4 candidates are prioritized before status 3 Zone A adults, whereas under the other scheme, status 3 Zone A adults are prioritized ahead of local status 4 adults.

LVAD patients using the discretionary 30 day status 3 time exhibit a lower waiting list mortality rate than the other groups that qualify for status 3, though the mortality rate for LVAD for 30 day patients appeared similar to candidates with some device complications and infections. Additionally, these candidates have similar waiting list mortality rates to candidates on inotropes without hemodynamic monitoring, who fall into status 4.

The Committee debated whether LVAD for 30 day candidates should be in Status 3. Ultimately, the Committee determined that the discretionary LVAD for 30 days policy should continue. Once the 30 day period expires, these candidates will be qualified for status 4. Under the proposed broader sharing scheme, the status 4 transplant rates are expected to be higher, which also benefits the stable LVAD patients in status 4 by providing them with quicker access to transplant, and decreases the risk that the stable LVAD patients will develop a complication before transplant.

Based on the analyses described above, the Committee anticipates the proposed policies will decrease waiting list mortality rates by increasing transplant rates for the most urgent candidates by ensuring they are properly escalated to the most urgent status, and have access to the broadest range of donors. Such changes are not anticipated to negatively impact waiting list mortality rates for candidates in less urgent statuses. Additionally, while post-transplant mortality rates may increase slightly for the most urgent candidates, the Committee believes this is an appropriate risk in order to benefit the most the candidates most in need.

Which populations are impacted by this proposal?

All heart and heart-lung candidates will be impacted by this proposal. As of December 4, 2015, there are 4,211 heart candidates and 49 heart-lung candidates awaiting transplant.

This proposal mainly impacts adult heart candidates. The Committee does not anticipate this proposal will have a negative impact on pediatric candidates, and may even have a positive impact on pediatric access to heart transplant. Though the number of pediatric candidates is small and therefore more difficult to analyze, the TSAM analysis shows total increased transplant counts for pediatric candidates under the 6 urgency status with broader sharing scheme, and the transplant rate for pediatric status 1A candidates increased. The overall death counts also decrease slightly.

How does this proposal support the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal.
2. *Improve equity in access to transplants:* Revising the heart allocation system will provide more equitable access to transplants based on medical urgency and on geographic location. The proposal is primarily aligned with this strategic goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* Waiting list mortality rates for adult heart candidates are expected to improve under the proposed policy, as candidates most in need of transplant will be transplanted more quickly and therefore not dying while waiting for a transplant. Overall post-transplant mortality may increase slightly as more urgent candidates are transplanted at increased rates.
4. *Promote living donor and transplant recipient safety:* There is no impact to this goal.
5. *Promote the efficient management of the OPTN:* The proposed statuses may decrease the number of exception requests that are submitted to the regional review boards, because the new statuses incorporated into policy the conditions for many groups of candidates that previously

applied for exceptions. Decreasing the number of exception requests will help the OPTN operate more efficiently by reducing staff time spent processing the requests, and reducing the amount of volunteer time required for regional review board members to review the requests.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

The Thoracic Committee will review waiting list and transplant data for all ages to ensure that this change in allocation serves its intended purpose without negatively impacting pre- or post-transplant outcomes for pediatric candidates/recipients. Outcomes in other populations may be assessed for unintended consequences as warranted; stratifications that may be considered include gender and race.

Since external factors and other changes in transplant policy can have an influence on the period following policy implementation, interpreting the apparent impact of this policy change based on "before vs. after" analysis must be done with caution.

Questions that will need to be answered as policy evaluation:

The following questions, and any others subsequently requested by the Committees, will guide the evaluation of the proposal after implementation.

- Have death rates for adult candidates on the heart waiting list decreased?
- Have transplant rates for adult candidates on the heart waiting list increased?
- Have post-transplant survival rates for adult heart recipients changed?
- Has the zonal distribution of heart transplants changed?
- Has the number of exception requests decreased?
- Has the heart utilization rate increased?

Data used to evaluate the proposal (Policy Performance Measures):
The following metrics, and any others subsequently requested by the Committee, will be used to evaluate the proposal. These metrics will be provided for the post-policy period, and compared to the pre-policy period, where possible. For pre- and post-policy comparisons involving medical urgency status, an approximate correspondence will be used: current status 1A compared to proposed statuses 1-3, and current status 1B compared to proposed tiers 4 and 5.

- Waiting list additions stratified by:
  - Medical urgency status
  - Criteria within medical urgency status
  - Region
  - Medical urgency status within Region
- Waiting list death rates stratified by:
  - Medical urgency status
  - Criteria within medical urgency status
  - Region
  - Medical urgency status within Region
- Waiting list transplant rates stratified by:
  - Medical urgency status
  - Criteria within medical urgency status
  - Region
  - Medical urgency status within Region
- Transplants stratified by:
  - Medical urgency status
  - Criteria within medical urgency status
  - Region
  - Medical urgency status within Region
  - Zone (DSA, Zone A, Zone B, etc.)

- Post-transplant patient survival stratified by:
  - Medical urgency status
  - Criteria within medical urgency status
  - Region
  - Medical urgency status within Region
  - Zone (DSA, Zone A, Zone B, etc.)
- Exception requests stratified by:
  - Medical urgency status
  - Region
  - Medical urgency status within Region
- Utilization of deceased donor hearts stratified by:
  - Donor age
  - Region

Timeline for evaluation:
The initial data analysis will be performed after the policy has been in place for about 6 months. Data will be evaluated no more frequently than every 6 months for the first two years and annually thereafter until 5 years post-implementation. Timeline is subject to change based on the results.

How will the OPTN implement this proposal?

This proposal will require a significant level of effort to program the new status criteria and sharing schemes in UNet^{SM}. Prior to implementation, the OPTN will provide transplant programs with a timeframe in which to update current candidates' information in UNet according to the new policy requirements. On the day of implementation, UNet will allocate organs using the new information. According to existing policy, within 24 hours of the implementation date, transplant programs should verify that their candidates' information is up-to-date in UNet, to ensure that their candidates are registered in the appropriate new urgency status. Candidates whose records are not updated by the time of implementation will appear in status 6 (or status 5 if the candidate is registered at the same transplant hospital for another organ).

Exceptions that are approved prior to implementation and exception requests that are in progress at the time of implementation will be ineffective upon implementation. Many of the exception requests are expected to be unnecessary upon implementation, because the proposed policy is intended to accommodate the conditions of many candidates who previously needed an exception.

The OPTN will ensure that waiting time accumulated under the old system will transition to the new system so that candidates already waiting will not be disadvantaged on the date of implementation. Waiting time will transfer and accumulate according to **Table 4**, below.

Table 4: Waiting Time Transfer and Accumulation

New Status	Waiting Time Calculated As
Status 1	Accumulated time at New Status 1 Plus accumulated time at Status 1A*
Status 2	Accumulated time at New Status 2 Plus accumulated time at New Status 1 Plus accumulated Time at Status 1A*
Status 3	Accumulated time at New Status 3 Plus accumulated time at New Status 2 Plus accumulated time at New Status 1 Plus accumulated time at Status 1A*
Status 4	Accumulated time at New Status 4 Plus accumulated time at New Status 3 Plus accumulated time at New Status 2 Plus accumulated time at New Status 1 Plus accumulated time at Status 1A* Plus accumulated time at Status 1B
Status 5	Accumulated time at New Status 5 Plus accumulated time at New Status 4 Plus accumulated time at New Status 3 Plus accumulated time at New Status 2 Plus accumulated time at New Status 1 Plus accumulated time at Status 1A* Plus accumulated time at Status 1B Plus accumulated Time at Old Status 2
Status 6	Accumulated time at New Status 6 Plus accumulated time at New Status 5 Plus accumulated time at New Status 4 Plus accumulated time at New Status 3 Plus accumulated time at New Status 2 Plus accumulated time at New Status 1 Plus accumulated time at Status 1A* Plus accumulated time at Status 1B Plus accumulated Time at Old Status 2 (same as total Waiting Time minus any Inactive Time)

*Accumulated time a status 1A includes any pre-January 1999 status 1 time.

The OPTN will educate members prior to implementation to ensure that all members know how to transition their patients to the new system.

How will members implement this proposal?

Members will need to update data for candidates registered on the waiting list prior to full implementation. Within 24 hours of implementation, members will need to verify their candidates' information is correct, and reflects the new requirements in the proposed policy to ensure that their candidate is registered at the most appropriate status.

Will this proposal require members to submit additional data?

This proposal requires members to submit additional data to justify candidate registrations at various statuses. These additional data will also help the Committee further stratify candidates in future modifications to this policy, or in development of a heart allocation system.

On multiple occasions, the Committee discussed how to identify and prioritize sensitized patients. Though the Committee discussed multiple solutions, including review board exceptions or prioritization for candidates with a Calculated Panel Reactive Antibody (CPRA) of 80 percent and with three positive prospective crossmatches, the problem remains that the OPTN does not collect sufficient data on heart patients to strongly support any of these solutions. The Committee decided instead to focus on collecting data so that in the future the Committee can make a more informed, evidenced-based decision on how policy should treat sensitized candidates. The Committee proposes collecting CPRA at the time of candidate's registration in Waitlist, and at the time of removal from Waitlist. Capturing CPRA at two discrete times will help the committee track a candidate's course while waiting for an organ. Capturing CPRA at removal for all candidates will help the committee understand how sensitization affects all candidates registered for a heart, not just those who actually receive a transplant. CRPA at time of transplant is already collected as of March 2015.

Transplant programs will be required to report CPRA at time of registration by entering the candidate's CPRA on the registration form. The CPRA will not be calculated by the system; the transplant hospital will obtain the candidate's CPRA from the histocompatibility lab and complete this section on the form. Upon removal, the same field will appear. Again, the system will not calculate the patient's CPRA at time of removal; the hospital will be responsible for obtaining this value from the lab and reporting it to the OPTN.

In the meantime, the current policy (Policy 6.3.B: *Exceptions to Allocation for Sensitized Patients*) will remain in place, and the Committee will emphasize the need for collaboration within DSAs for prioritizing sensitized candidates.

How will members be evaluated for compliance with this proposal?

The proposed policy modifications will not affect the methods by which UNOS staff routinely review members, but the content of the review may change based on the proposed modifications.

UNOS staff will continue to review all deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN requirements and will continue to investigate potential policy violations.

At transplant hospitals, site surveyors will continue to review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:

- Information reported on the adult status justification form is consistent with source documentation
- The candidate met the requirements for the qualifying criterion selected on the adult status justification form and any required sub-criteria

- The candidate's medical urgency status or qualifying criteria used to justify the status were updated in UNet℠ within 24 hours of a change in the candidate's medical condition to accurately reflect the change in condition

Policy or Bylaw Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

6.1 Adult Status Assignments and Update Requirements

Each adult heart transplant candidate at least 18 years old at the time of registration is assigned a status that reflects the candidate's medical urgency for transplant. Adult heart candidates on the waiting list that are not currently suitable for transplant are assigned inactive status.

~~Heart candidates at least 18 years old at the time of registration may be assigned *any* of the following:~~

- ~~Adult status 1A~~
- ~~Adult status 1B~~
- ~~Adult status 2~~
- ~~Inactive status~~

If a candidate's medical condition changes and the criteria used to justify that candidate's status is no longer accurate, then the candidate's transplant program must update the candidate's status and report the updated information to the OPTN Contractor within 24 hours of the change in medical condition.

If a candidate's status justification form expires and the transplant program does not submit a new status justification form, the candidate is automatically assigned to status 6, or status 5 if the candidate is registered for another organ.

6.1.A Adult Heart Status 1A Requirements

To assign a candidate to adult status 1A, the candidate's transplant program must submit a *Heart Status 1 Justification Form* to the OPTN Contractor. A candidate is not assigned to adult status 1 until this form is submitted.

If the candidate is at least 18 years old at the time of registration then the candidate's transplant program may assign the candidate to adult status 1 if the candidate has at least *one* ~~*either*~~ of the following conditions:

- Is supported by veno-arterial extracorporeal membrane oxygenation, according to *Policy 6.1.A.i* below.
- Is supported by continuous mechanical ventilation according to *Policy 6.1.A.ii* below.
- Is supported by a non-dischargeable ventricular assist device according to *Policy 6.1.A.iii* below.
- Is supported by a mechanical circulatory support device and has a life-threatening ventricular arrhythmia according to *Policy 6.1.A.iv* below.

6.1.A.i Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)

The candidate is admitted to the transplant hospital that registered the candidate on the waiting list and supported by VA ECMO.

This status is valid for up to 14 days from submission of *the Heart Status 1 Justification Form*. This status can be recertified by the transplant program every 14 days by submission of another *Heart Status 1 Justification Form*.

6.1.A.ii Continuous Mechanical Ventilation

The candidate is admitted to the transplant hospital that registered the candidate on the waiting list and is supported by continuous mechanical ventilation with endotracheal intubation.

This status is valid for up to 14 days from submission of *the Heart Status 1 Justification Form*. This status can be recertified by the transplant program every 14 days by submission of another *Heart Status 1 Justification Form*.

6.1.A.iii Non-Dischargeable Ventricular Assist Device (VAD)

The candidate is admitted to the transplant hospital that registered the candidate on the waiting list and is supported by a surgically implanted, non-dischargeable VAD. The OPTN Contractor maintains a list of OPTN-approved, qualifying non-dischargeable, surgically implanted VADs.

This status is valid for up to 14 days from submission of *the Heart Status 1 Justification Form*. This status can be recertified by the transplant program every 14 days by submission of another *Heart Status 1 Justification Form*.

6.1.A.iv Mechanical Circulatory Support Device (MCSD) with Life-Threatening Ventricular Arrhythmia

The candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by an MCSD, and is experiencing recurrent or sustained ventricular tachycardia or ventricular fibrillation as evidenced by *at least one* of the following:

Placement of biventricular mechanical circulatory support for the treatment of sustained ventricular arrhythmias

That the patient was not considered a candidate for other treatment alternatives, such as ablation, by an electrophysiologist and has experienced three or more episodes of ventricular fibrillation or ventricular tachycardia separated by at least an hour, over the previous 14 days that *both*:

- Occurred in the setting of normal serum magnesium and potassium levels
- Required electrical cardioversion in a candidate receiving antiarrhythmic therapies

This status is valid for up to 14 days from submission of *the Heart Status 1 Justification Form*. After the initial 14 days, this status can be recertified by the transplant program every 14 days by submission of another *Heart Status 1 Justification Form*.

To extend this status for an additional 14 day period, the patient must remain hospitalized on intravenous anti-arrhythmic therapy.

~~1. The candidate is admitted to the transplant hospital that registered the candidate on the waiting list, or an affiliated Veteran's Administration (VA) hospital, and the candidate also meets at least *one* of the requirements in *Table 6-1* below.~~

Table 6-1: Adult Status 1A Requirements for Candidates Currently Admitted to the Transplant Hospital

If the candidate meets this condition:	Then adult status 1A is valid for:
Has one of the following mechanical circulatory support devices in place: • **Total artificial heart (TAH)** • **Intra-aortic balloon pump** • **Extracorporeal membrane oxygenation (ECMO)**	14 days, and must be recertified by an attending physician every 14 days from the date of the candidate's initial registration as adult status 1A to extend the adult status 1A registration.
Requires continuous mechanical ventilation	14 days, and must be recertified by an attending physician every 14 days from the date of the candidate's initial registration as adult status 1A to extend the Status 1A registration.
Requires continuous infusion of a single high-dose intravenous inotrope or multiple intravenous inotropes, and requires continuous hemodynamic monitoring of left ventricular filling pressures. The OPTN Contractor will maintain a list of the OPTN-approved qualifying inotropes and doses.	7 days, and may be renewed for additional 7 day periods for each occurrence of an adult status 1A listing under this criterion for this candidate.

A candidate who is at least 18 years old at the time of registration, and may or may not be currently admitted to the transplant hospital, may be assigned adult status 1A if the candidate meets at least *one* of the requirements in *Table 6-2* below.

Table 6-2: Adult Status 1A Requirements for Candidates - Current Hospitalization Not Required

If the candidate meets this condition:	Then the status is valid for:
Has *one* of the following mechanical circulatory support devices in place: • **Left ventricular assist device (LVAD)** • **Right ventricular assist device (RVAD)** • **Left and right ventricular assist devices (BiVAD)**	30 days, and the candidate may be registered as adult status 1A for 30 days at any point after being implanted once an attending physician determines the candidate is medically stable. The 30 days do not have to be consecutive. However, if the candidate undergoes a procedure to receive another device, then the candidate qualifies for a new term of 30 days. Any 30 days granted by the new device would substitute and not supplement any time remaining from the previous adult status 1A classification.

~~If the candidate meets this condition:~~	~~Then the status is valid for:~~
~~**Candidate has mechanical circulatory support and there is medical evidence of significant device-related complications including, but not limited to, thromboembolism, device infection, mechanical failure, or life-threatening ventricular arrhythmias. A candidate's sensitization is not an acceptable device-related complication to qualify as adult status 1A. If a transplant program reports a complication that is not listed here, the registration will be retrospectively reviewed by the heart regional review board (RRB)**~~	~~14 days, and must be recertified by an attending physician every 14 days from the date of the candidate's initial registration as adult status 1A to extend the adult status 1A registration.~~

~~If the attending physician does not update the qualifications for adult status 1A registration when required according to *Tables 6-1* and *6-2* above, then the candidate's adult status 1A will expire and the candidate will be downgraded to adult status 1B.~~

6.1.B Adult Heart Status 2 ~~Status 1B~~ Requirements

To assign a candidate to adult status 2 ~~status 1B~~, the candidate's transplant program must submit a *Heart Status 2 ~~Status 1B~~ Justification Form* to the OPTN Contractor. A candidate is not assigned adult Status 2 ~~status 1B~~ until this form is submitted.

~~The candidate's transplant program may assign the candidate as adult status 1B i~~ If the candidate is at least 18 years old at the time of registration then the candidate's transplant program may assign the candidate to adult status 2 if ~~and has~~ the candidate has at least *one* of the following conditions:

- Is supported by a total artificial heart or bi-ventricular assist device (BiVAD) with ventriculectomy, according to *Policy 6.1.B.i* below.
- Is supported by a dischargeable BiVAD or right ventricular assist device, or is a single ventricle patient and is supported by a dischargeable left ventricular assist device, according to *Policy 6.1.B.ii* below.
- Is supported by a mechanical circulatory support device that is malfunctioning, according to *Policy 6.1.B.iii* below.
- Is supported by an acute circulatory support device, according to *Policy 6.1.B.iv* below.
- Is supported by an intra-aortic balloon pump, according to *Policy 6.1.B.v* below.
- Is experiencing recurrent or sustained ventricular tachycardia or ventricular fibrillation according to *Policy 6.1.B.vi* below.

6.1.B.i Total Artificial Heart or Bi-VAD with Ventriculectomy

The candidate is supported by a total artificial heart or a BiVAD with ventriculectomy.

This status does not require any recertification.

6.1.B.ii Dischargeable BiVAD, Right Ventricular Assist Device (RVAD), or Dischargeable Left Ventricular Assist Device (LVAD) for Single Ventricle Patients

The candidate is supported *any* of the following:

- A dischargeable RVAD
- A dischargeable BiVAD without ventriculectomy
- A dischargeable LVAD, for single ventricle patients only

The OPTN Contractor maintains a list of OPTN-approved, qualifying devices.

This status is valid for up to 14 days from submission of *the Heart Status 2 Justification Form*. After the initial 14 days, this status can be recertified by the transplant program every 14 days by submission of another *Heart Status 2 Justification Form*.

6.1.B.iii Mechanical Circulatory Support Device (MCSD) with Malfunction

The candidate is admitted to the transplant hospital that registered the candidate on the waiting list and is supported by an MCSD that is experiencing device malfunction as evidenced by *all* of the following:

1. Malfunction of at least one of the components of the MCSD
2. Malfunction cannot be fixed without an entire device replacement
3. Malfunction that is currently causing inadequate circulatory support or places the candidate at imminent risk of VAD stoppage

This status is valid for up to 14 days from submission of *the Heart Status 2 Justification Form*. After the initial 14 days, this status can be recertified by the transplant program every 14 days by submission of another *Heart Status 2 Justification Form*.

6.1.B.iv Acute Circulatory Support (ACS) Device

The candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by an ACS device for cardiogenic shock, and had a cardiac index of less than or equal to 2.2 L/min/m^2 within 7 days prior to implant. The OPTN Contractor maintains a list of OPTN-approved, qualifying ACS devices.

This status is valid for up to 14 days from submission of *the Heart Status 2 Justification Form*. After the initial 14 days, this status can be recertified by the transplant program every 14 days by submission of another *Heart Status 2 Justification Form*.

6.1.B.v Intra-Aortic Balloon Pump (IABP)

The candidate is admitted to the transplant hospital that registered the candidate on the waiting list and is supported by an IABP for cardiogenic shock, and had a cardiac index of less than or equal to 2.2 L/min/m^2 within 7 days prior to insertion.

This status is valid for up to 14 days from submission of *the Heart Status 2 Justification Form*. After the initial 14 days, this status can be recertified by the transplant program every 14 days by submission of another *Heart Status 2 Justification Form*.

6.1.B.vi Ventricular Tachycardia (VT) or Ventricular Fibrillation (VF)

The candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is not considered a candidate for other treatment alternatives such as

ablation, and is experiencing recurrent or sustained VT or VF with at least three episodes separated by at least an hour for a period of 14 days. The VT or VF episodes must have *both*:

1. Occurred in the setting of normal serum magnesium and potassium levels
2. Required electrical cardioversion in a candidate receiving intravenous antiarrhythmic therapies

This status is valid for up to 14 days from submission of *the Heart Status 2 Justification Form*. After the initial 14 days, this status can be recertified by the transplant program every 14 days by submission of another *Heart Status 2 Justification Form* documenting that the candidate meets the criteria above or that the candidate remains hospitalized on intravenous anti-arrhythmic therapy.

~~1. Left ventricular assist device (LVAD)~~
~~2. Right ventricular assist device (RVAD)~~
~~3. Left and right ventricular assist devices (BiVAD)~~
~~4. Continuous infusion of intravenous inotropes~~

~~Candidates that continue to qualify for adult status 1B may retain this status for an unlimited period and this status does not require any recertification, unless the candidate's medical condition changes as described in *Policy 6.2: Status Updates*.~~

6.1.C Adult Heart Status 3 ~~Status 2~~ Requirements

To assign a candidate to adult status 3, the candidate's transplant program must submit a *Heart Status 3 Justification Form* to the OPTN Contractor. A candidate is not assigned adult status 3 until this form is submitted.

If the candidate is at least 18 years old at the time of registration then the candidate's transplant program may assign the candidate adult status 3 if the candidate has at least *one* of the following conditions:

- Is supported by a dischargeable left ventricular assist device and is exercising 30 days of discretionary time, according to *Policy 6.1.C.i* below.
- Is supported by multiple inotropes or a single high dose inotrope and has hemodynamic monitoring, according to *Policy 6.1.C.ii* below.
- Is supported by a mechanical circulatory support device (MCSD) with hemolysis, according to *Policy 6.1.C.iii* below.
- Is supported by an MCSD with pump thrombosis, according to *Policy 6.1.C.iv* below.
- Is supported by an MCSD and has right heart failure, according to *Policy 6.1.C.v* below.
- Is supported by an MCSD and has a device infection, according to *Policy 6.1.C.vi* below.
- Is supported by an MCSD and has bleeding, according to *Policy 6.1.C.vii* below.
- Is supported by an MCSD and has aortic insufficiency, according to *Policy 6.1.C.viii* below.

~~If the candidate is at least 18 years old at the time of registration and does not meet the criteria for adult status 1A or 1B but is suitable for transplant, then the candidate may be assigned adult status 2.~~

6.1.C.i Dischargeable Left Ventricular Assist Device (LVAD) for Discretionary 30 Days

The candidate is supported by a dischargeable LVAD. The OPTN Contractor maintains a list of OPTN-approved, qualifying devices.

The candidate may be registered as status 3 for 30 days at any point after being implanted with the dischargeable LVAD and once the attending physician determines the candidate is medically stable. Regardless of whether the candidate has a single transplant program registration or multiple transplant program registrations, the candidate receives a total of 30 days discretionary time for each dischargeable LVAD implanted across all registrations. Each day used by any of the transplant programs counts towards the cumulative 30 days.

The 30 days do not have to be consecutive and if the candidate undergoes a procedure to receive another replacement dischargeable LVAD, then the candidate qualifies for a new term of 30 days. When a candidate receives a replacement device, the 30 day period begins again, and the candidate cannot use any time remaining from the previous period.

6.1.C.ii Multiple Inotropes or a Single High Dose Inotrope and Hemodynamic Monitoring

The candidate is admitted to the hospital that registered the candidate on the waiting list, had a cardiac index of less than or equal to 2.2 L/min/m^2 within 7 days prior to inotrope administration or while on inotropes, and meets *both* of the following:

1. Has *one* of the following:
    - Invasive pulmonary artery catheter
    - Daily hemodynamic monitoring to measure cardiac output and left ventricular filling pressures
2. Is supported by *one* of the following:
    - A continuous infusion of *at least one* high-dose intravenous inotrope
        - Dobutamine greater than or equal to 7.5 mcg/kg/min
        - Milrinone greater than or equal to 0.50 mcg/kg/min
        - Epinephrine greater than or equal to 0.02 mcg/kg/min
    - A continuous infusion of *at least two* multiple intravenous inotropes
        - Dobutamine greater than or equal to 3 mcg/kg/min
        - Milrinone greater than or equal to 0.25 mcg/kg/min
        - Epinephrine greater than or equal to 0.01 mcg/kg/min
        - Dopamine greater than or equal to 3 mcg/kg/min

This status is valid for up to 14 days from submission of *the Heart Status 3 Justification Form.* After the initial 14 days, this status can be recertified by the transplant program every 14 days by submission of another *Heart Status 3 Justification Form* if the candidate remains admitted to the hospital that registered the candidate on the waiting list, and the candidate remains supported by ongoing use of the qualifying inotrope therapy and *at least one* of the following:

- Invasive pulmonary artery catheter
- Cardiac index less than 2.2 L/min/m^2 on the current medical regimen
- Failed attempt to wean the inotrope support documented by *one* of the following:
    - Cardiac index less than 2.2 L/min/m^2 during dose reduction
    - Increase in serum creatinine by 20% over the value immediately prior to, and within 24 hours of, inotrope dose reduction
    - Increase in arterial lactate to greater than 2.5 mmol/L

6.1.C.iii Mechanical Circulatory Support Device (MCSD) with Hemolysis

The candidate is supported by an MCSD and is not experiencing device malfunction, but is experiencing hemolysis, as evidenced by *all* of the following:

- Two separate blood samples measured within 48 hours of each other confirming markers of active hemolysis as evidenced by *at least two* of the following criteria:
  - Lactate dehydrogenase (LDH) at least 2.5 times the upper limit of normal at the laboratory reference range
  - Plasma free hemoglobin greater than 20 mg/dL
  - Hemoglobinuria
- Documentation of at least one attempt to treat the condition using an intravenous anticoagulant, intravenous anti-platelet agent, or thrombolytic, with persistent or recurrent hemolysis

This status is valid for up to 14 days from submission of *the Heart Status 3 Justification Form*. After the initial 14 days, this status can be recertified by the transplant program every 14 days by submission of another *Heart Status 3 Justification Form*.

6.1.C.iv Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis

The candidate is supported by an MCSD and is experiencing pump thrombosis as evidenced by *at least one* of the following:

- Visually detected thrombus in a paracorporeal ventricular assist device (VAD)
- Transient ischemic attack, stroke, or peripheral thromboembolic event, non-invasive testing to exclude intracardiac thrombus in all candidates, and significant carotid artery disease in candidates with a neurological event

This status is valid for up to 14 days from submission of *the Heart Status 3 Justification Form*. After the initial 14 days, this status can be recertified by the transplant program every 14 days by submission of another *Heart Status 3 Justification Form*.

6.1.C.v Mechanical Circulatory Support Device (MCSD) with Right Heart Failure

The candidate is supported by an MCSD and has at least moderate right ventricular malfunction in the absence of left ventricular assist device (LVAD) malfunction, and *all* of the following:

1. Has been treated for at least 14 days, and requires ongoing treatment with *at least one* of the following therapies:
   - Dobutamine greater than or equal to 5 mcg/kg/min
   - Dopamine greater than or equal to 4 mcg/kg/min
   - Epinephrine greater than or equal to 0.05 mcg/kg/min
   - Inhaled nitric oxide
   - Intravenous prostacyclin
   - Milrinone greater than or equal to 0.35 mcg/kg/min

2. Has, within 7 days prior to initiation of therapy, pulmonary capillary wedge pressure less than 20 mm Hg and central venous pressure greater than 18 mm Hg

This status is valid for up to 14 days from submission of *the Heart Status 3 Justification Form.* After the initial 14 days, this status can be recertified by the transplant program every 14 days by submission of another *Heart Status 3 Justification Form*.

6.1.C.vi Mechanical Circulatory Support Device (MCSD) with Device Infection

The candidate is supported by an MCSD and is experiencing a pump-related local or systemic infection, with *at least one* of symptoms according to *Table 6-1: Evidence of Device Infection* Below.

Table 6-1: Evidence of Device Infection

If the candidate has evidence of:	Then this status is valid:
Erythema and pain along the driveline, with either leukocytosis or a 50 percent increase in white blood cell count from the last recorded white blood cell count, and *either*: • Positive bacterial or fungal cultures from the driveline exit site within the last 14 days • A culture-positive fluid collection between the exit site and the device	For 14 days from submission of *the Heart Status 3 Justification Form*.
Debridement of the driveline with positive cultures from sites between the exit site and the device	For 14 days from submission of *the Heart Status 3 Justification Form*.
Bacteremia treated with antibiotics	For 6 weeks from submission of *the Heart Status 3 Justification Form*.
Recurrent bacteremia that recurs from the same organism within four weeks following antibiotic treatment to which the bacteria is susceptible	As long as the candidate meets the criteria.
Positive culture of material from the pump pocket of an implanted device	As long as the candidate meets the criteria.

6.1.C.vii Mechanical Circulatory Support Device (MCSD) with Mucosal Bleeding

The candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by an MCSD, has been hospitalized for mucosal bleeding at least two times within the past six months, excluding the candidate's hospitalization for implantation of the MCSD, and meets *at least one* of the requirements according to *Table 6-2: Evidence of Mucosal Bleeding* below.

Table 6-2: Evidence of Mucosal Bleeding

If *all* of the following occurred:	Then this status is valid for *either*:
1. The candidate received blood transfusions of at least two units of packed red blood cells per hospitalization during at least two hospitalizations for mucosal bleeding 2. The candidate's international normalized ratio (INR) was less than 3.0 at the time of at least one of the bleeds 3. The candidate's hematocrit upon admission is less than or equal to 0.20 or decreased by 20 percent or more relative to the last measured value at any time during the bleeding episode	• 14 days from submission of *the Heart Status 3 Justification Form*, if the candidate has been hospitalized for mucosal bleeding at least two times within the past six months • 90 days from submission of *the Heart Status 3 Justification Form*, if the candidate has been hospitalized at least three times within the past six months

6.1.C.viii Mechanical Circulatory Support Device (MCSD) with Aortic Insufficiency (AI)

The candidate is supported by an MCSD and is not exhibiting evidence of device malfunction, but is experiencing AI, with *all* of the following:

1. At least moderate AI by any imaging modality in the setting of the mean arterial pressure (MAP) less than or equal to 80 mm Hg
2. Pulmonary capillary wedge pressure greater than 20 mm Hg
3. New York Heart Association (NYHA) Class III-IV symptoms

This status is valid as long as the candidate meets the above criteria.

~~The candidate may retain adult status 2 for an unlimited period and this status does not require recertification, unless the candidate's medical condition changes as described in *Policy 6.2: Status Updates*.~~

6.1.D Adult Heart Status 4 Requirements

To assign a candidate adult status 4, the candidate's transplant program must submit a *Heart Status 4 Justification Form* to the OPTN Contractor. A candidate is not assigned adult status 4 until this form is submitted.

If the candidate is at least 18 years old at the time of registration then the candidate's transplant program may assign the candidate adult status 4 if the candidate has at least *one* of the following conditions:

- Is supported by a dischargeable left ventricular assist device (LVAD), according to *Policy 6.1.D.i* below.
- Is supported by inotropes without continuous hemodynamic monitoring, according to *Policy 6.1.D.ii* below.
- Is diagnosed with congenital heart disease, according to *Policy 6.1.D.iii* below.
- Is diagnosed with ischemic heart disease with intractable angina, according to *Policy 6.1.D.iv* below.

- Is diagnosed with Amyloidosis, hypertrophic cardiomyopathy or restrictive cardiomyopathy, according to *Policy 6.1.D.v* below.
- Is a re-transplant, according to *Policy 6.1.D.vi* below.

6.1.D.i Dischargeable Left Ventricular Assist Device (LVAD) without Discretionary 30 Days

The candidate is supported by a dischargeable LVAD. The OPTN Contractor maintains a list of OPTN-approved, qualifying devices.

This status is valid as long as the candidate meets the above criteria.

6.1.D.ii Inotropes without Hemodynamic Monitoring

The candidate is supported by a continuous infusion of a positive inotropic agent, had a cardiac index of less than or equal to 2.2 L/min/m^2 within seven days prior to inotrope initiation, and requires *at least one* of the following intravenous inotropes:

- Dobutamine greater than or equal to 3 mcg/kg/min
- Milrinone greater than or equal to 0.25 mcg/kg/min
- Epinephrine greater than or equal to 0.01 mcg/kg/min
- Dopamine greater than or equal to 3 mcg/kg/min

This status is valid as long as the candidate meets the above criteria.

6.1.D.iii Congenital Heart Disease

The candidate is diagnosed with a hemodynamically significant congenital heart disease. The OPTN Contractor maintains a list of OPTN-approved qualifying congenital heart disease diagnoses.

This status is valid as long as the candidate meets the above criteria.

6.1.D.iv Ischemic Heart Disease with Intractable Angina

The candidate is diagnosed with ischemic heart disease and has intractable angina, with *all* of the following:

1. Coronary artery disease
2. Canadian Cardiovascular Society Grade IV angina pectoris that cannot be treated by a combination of medical therapy, and percutaneous or surgical revascularization
3. Myocardial ischemia shown by imaging

This status is valid as long as the candidate meets the above criteria.

6.1.D.v Amyloidosis, or Hypertrophic or Restrictive Cardiomyopathy

The candidate is diagnosed with amyloidosis, hypertrophic cardiomyopathy or restrictive cardiomyopathy, with *at least one* of the following:

- Canadian Cardiovascular Society Grade IV angina pectoris that cannot be controlled by medical therapy
- NYHA Class III-IV symptoms with *either*:
  - Cardiac index less than 2.2 L/min/m^2
  - Left or right atrial pressure, left or right ventricular end-diastolic pressure, or pulmonary capillary wedge pressure greater than 20 mm Hg

- Ventricular tachycardia lasting at least 30 seconds
- Ventricular fibrillation
- Ventricular arrhythmia requiring electrical cardioversion
- Sudden cardiac death

This status is valid as long as the candidate meets the above criteria.

6.1.D.vi Re-transplant

The candidate has a previous heart transplant, and there is evidence of ISHLT coronary allograft vasculopathy (CAV) grade 2-3, or NYHA Class III-IV heart failure symptoms.

This status is valid as long as the candidate meets the above criteria.

6.1.E Adult Heart Status 5 Requirements

If the candidate is at least 18 years old at the time of registration then the candidate's transplant program may assign the candidate to adult status 5 if the candidate is registered on the heart waiting list, and is also registered on the waiting list for at least one other organ at the same hospital.

This status is valid as long as the candidate is registered for another organ at the same hospital.

6.1.F Adult Heart Status 6 Requirements

If the candidate is at least 18 years old at the time of registration and is suitable for transplant, then the candidate may be assigned to adult status 6.

This status is valid as the candidate is suitable for transplant.

6.2 Pediatric Status ~~Updates~~ Assignments and Update Requirements

Heart candidates less than 18 years old at the time of registration may be assigned any of the following:

- Pediatric status 1A
- Pediatric status 1B
- Pediatric status 2
- Inactive status

A candidate registered on the waiting list before turning 18 years old remains eligible for pediatric status until the candidate has been removed from the waiting list.

If a candidate's medical condition changes and the criteria used to justify that candidate's status is no longer accurate, then the candidate's transplant program must update the candidate's status and report the updated information to the OPTN Contractor within 24 hours of the change in medical condition.

6.~~1~~.2D Pediatric Heart Status 1A

[*Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.*]

6.3 Adult and Pediatric Status Exceptions

A heart candidate can receive a status by qualifying for an exception according to *Table 6-3* below.

Table 6-3: Exception Qualification and Periods

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
Adult ~~status 1A~~ status 1	1. Candidate is admitted to the transplant hospital that registered the candidate on the waiting list 2. Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested ~~status~~ status	RRBs retrospectively review requests for status 1~~Status 1A~~ exceptions	14 days	• Require RRB approval for each successive 14 day period • RRB will review and decide extension requests retrospectively • ~~If no extension request is submitted, the candidate will be assigned adult status 1B~~
Adult status 2 ~~status 1B~~	1. Candidate is admitted to the transplant hospital that registered the candidate on the waiting list 2. Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	RRBs retrospectively review requests for status 2~~Status 1B~~ exceptions	~~Indefinite~~ 14 days	• Require RRB approval for each successive 14 day period • RRB will review and decide extension requests retrospectively

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
Adult status 3	1. Candidate is admitted to the transplant hospital that registered the candidate on the waiting list 2. Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	RRBs retrospectively review requests for status 3 exceptions	14 days	• Require RRB approval for each successive 14 day period • RRB will review and decide extension requests retrospectively
Adult status 4	• Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	RRBs retrospectively review requests for status 4 exceptions	As long as the candidate's condition remains the same.	No extension is required
Pediatric status 1A	• Candidate is admitted to the transplant hospital that registered the candidate on the waiting list • Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	RRBs retrospectively review requests for Status 1Aexceptions	14 days	• Require RRB approval for each successive 14 day period • RRB will review and decide extension requests retrospectively • If no extension request is submitted, the candidate will be assigned pediatric status 1B

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
Pediatric status 1B	• Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	RRBs retrospectively review requests for Status 1B exceptions	Indefinite	• Not required as long as candidate's medical condition remains the same

The candidate's transplant physician must submit a justification form to the OPTN Contractor with the requested status and the rationale for granting the status exception.

6.3.A RRB and Committee Review of Status Exceptions

The heart RRB reviews all applications for adult status exceptions and pediatric status exceptions retrospectively.

6.~~3~~.A.i: RRB Appeals

If the RRB denies a request, the candidate's transplant program may appeal to the RRB. If the RRB denies the appeal and the candidate is transplanted at the unapproved status, the case will automatically be reviewed by the Thoracic Organ Transplantation Committee. The Thoracic Committee will review the RRB's decisions and rationale, and, if it agrees with the RRB's denial, will refer the case to the Membership and Professional Standards Committee (MPSC) for further review. If it disagrees with the RRB's denial, the request is considered approved and the candidate can be registered at the requested status. ~~If an adult status 1A exception request is not approved by the RRB, the candidate's transplant program may override the decision and list the candidate at the requested status.~~

6.3.A.ii: RRB Overrides

If a ~~pediatric status 1A or status 1B exception~~ request is not approved by the RRB, the candidate's transplant program may override the decision and ~~list~~ register the candidate at the requested status, subject to automatic review by the Thoracic ~~Organ Transplantation~~ Committee. The Thoracic ~~Organ Transplantation~~ Committee ~~may~~ will review the RRB's decisions and rationale, and consider whether the candidate was transplanted at the unapproved status, and whether the transplant program repeatedly overrides decisions of the RRB, and may refer the ~~and may refer any~~ case to the ~~Membership and Professional Standards Committee (~~MPSC~~)~~ for further review.

6.3.B Exceptions to Allocation for Sensitized Patients

A transplant program may allocate a heart to sensitized candidates within a DSA out of sequence within a status as defined in *Policy 6.5: Heart Allocation Classifications and Rankings* if:

1. The candidate's transplant surgeon or physician determines that the candidate's antibodies would react adversely to certain human leukocyte antigens (HLA).

2. All heart transplant programs and the OPO within the DSA agree to allocate a heart from a compatible deceased donor to the sensitized candidate.
3. The candidate's transplant program, all heart transplant programs, and the OPO within the DSA agree upon the level of sensitization at which a candidate qualifies for the sensitization exception.

Sensitization alone does not qualify a candidate to be assigned any status exception as described in *Policy 6.3* above.

6.4 Waiting Time

Waiting time for heart candidates begins when the candidate is first registered as an active heart candidate on the waiting list, and is calculated within each heart status.

If a candidate's status is upgraded, waiting time accrued while registered at the lower status is not transferred to the higher status. Conversely, waiting time accrued while registered at a higher status is transferred to a lower status if the candidate is ~~downgraded~~ transferred to a lower status.

Waiting time does not accrue while the candidate is inactive.

6.5 Heart Allocation Classifications and Rankings

6.5.C Sorting Within Each Classification

Candidates are sorted within each classification by the total amount of waiting time that the candidate has accumulated at that status, according to *Policy 6.4: Waiting Time*.

6.5.D Allocation of Hearts from Donors at Least 18 years Old

Hearts from deceased donors at least 18 years old are allocated to candidates according to *Table 6-8* below.

568 **Table 6-8: Allocation of Hearts from Deceased Donors At Least 18 Years Old**
569

Classification	Candidates that are within the:	And are:
1	OPO's DSA or Zone A	Adult status 1 or pediatric status 1A and primary blood type match with the donor
2	OPO's DSA or Zone A	Adult status 1 or pediatric status 1A and secondary blood type match with the donor
3	Zone B	Adult status 1 or pediatric status 1A and primary blood type match with the donor
4	Zone B	Adult status 1 or pediatric status 1A and secondary blood type match with the donor
5	OPO's DSA or Zone A	Adult status 2 and primary blood type match with the donor
6	OPO's DSA or Zone A	Adult status 2 and secondary blood type match with the donor
7	Zone B	Adult status 2 and primary blood type match with the donor
8	Zone B	Adult status 2 and secondary blood type match with the donor
9	OPO's DSA	Adult status 3 or pediatric status 1B and primary blood type match with the donor
10	OPO's DSA	Adult status 3 or pediatric status 1B and secondary blood type match with the donor
11	OPO's DSA	Adult status 4 and primary blood type match with the donor
12	OPO's DSA	Adult status 4 and secondary blood type match with the donor
13	Zone A	Adult status 3 or pediatric status 1B and primary blood type match with the donor
14	Zone A	Adult status 3 or pediatric status 1B and secondary blood type match with the donor
15	OPO's DSA	Adult status 5 and primary blood type match with the donor
16	OPO's DSA	Adult status 5 and secondary blood type match with the donor
17	Zone B	Adult status 3 or pediatric status 1B and primary blood type match with the donor
18	Zone B	Adult status 3 or pediatric status 1B and secondary blood type match with the donor
19	OPO's DSA	Adult status 6 or pediatric status 2 and primary blood type match with the donor
20	OPO's DSA	Adult status 6 and pediatric status 2 and secondary blood type match with the donor
21	Zone C	Adult status 1 or pediatric status 1A and primary blood type match with the donor

Classification	Candidates that are within the:	And are:
22	Zone C	Adult status 1 or pediatric status 1A and secondary blood type match with the donor
23	Zone C	Adult status 2 and primary blood type match with the donor
24	Zone C	Adult status 2 and secondary blood type match with the donor
25	Zone C	Adult status 3 or pediatric status 1B and primary blood type match with the donor
26	Zone C	Adult status 3 or pediatric status 1B and secondary blood type match with the donor
27	Zone A	Adult status 4 and primary blood type match with the donor
28	Zone A	Adult status 4 and secondary blood type match with the donor
29	Zone A	Adult status 5 and primary blood type match with the donor
30	Zone A	Adult status 5 and secondary blood type match with the donor
31	Zone A	Adult status 6 or pediatric status 2 and primary blood type match with the donor
32	Zone A	Adult status 6 or pediatric status 2 and secondary blood type match with the donor
33	Zone D	Adult status 1 or pediatric status 1A and primary blood type match with the donor
34	Zone D	Adult status 1 or pediatric status 1A and secondary blood type match with the donor
35	Zone D	Adult status 2 and primary blood type match with the donor
36	Zone D	Adult status 2 and secondary blood type match with the donor
37	Zone D	Adult status 3 or pediatric status 1B and primary blood type match with the donor
38	Zone D	Adult status 3 or pediatric status 1B and secondary blood type match with the donor
39	Zone B	Adult status 4 and primary blood type match with the donor
40	Zone B	Adult status 4 and secondary blood type match with the donor
41	Zone B	Adult status 5 and primary blood type match with the donor
42	Zone B	Adult status 5 and secondary blood type match with the donor
43	Zone B	Adult status 6 or pediatric status 2 and primary blood type match with the donor

Classification	Candidates that are within the:	And are:
44	Zone B	Adult status 6 or pediatric status 2 and secondary blood type match with the donor
45	Zone E	Adult status 1 or pediatric status 1A and primary blood type match with the donor
46	Zone E	Adult status 1 or pediatric status 1A and secondary blood type match with the donor
47	Zone E	Adult status 2 and primary blood type match with the donor
48	Zone E	Adult status 2 and secondary blood type match with the donor
49	Zone E	Adult status 3 or pediatric status 1B and primary blood type match with the donor
50	Zone E	Adult status 3 or pediatric status 1B and secondary blood type match with the donor
51	Zone C	Adult status 4 and primary blood type match with the donor
52	Zone C	Adult status 4 and secondary blood type match with the donor
53	Zone C	Adult status 5 and primary blood type match with the donor
54	Zone C	Adult status 5 and secondary blood type match with the donor
55	Zone C	Adult status 6 or pediatric status 2 and primary blood type match with the donor
56	Zone C	Adult status 6 or pediatric status 2 and secondary blood type match with the donor
57	Zone D	Adult status 4 and primary blood type match with the donor
58	Zone D	Adult status 4 and secondary blood type match with the donor
59	Zone D	Adult status 5 and primary blood type match with the donor
60	Zone D	Adult status 5 and secondary blood type match with the donor
61	Zone D	Adult status 6 or pediatric status 2 and primary blood type match with the donor
62	Zone D	Adult status 6 or pediatric status 2 and secondary blood type match with the donor
63	Zone E	Adult status 4 and primary blood type match with the donor
64	Zone E	Adult status 4 and secondary blood type match with the donor
65	Zone E	Adult status 5 and primary blood type match with the donor

Classification	Candidates that are within the:	And are:
66	Zone E	Adult status 5 and secondary blood type match with the donor
67	Zone E	Adult status 6 or pediatric status 2 and primary blood type match with the donor
68	Zone E	Adult status 6 or pediatric status 2 and secondary blood type match with the donor

570
571

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~
~~1~~	~~OPO's DSA~~	~~Adult or pediatric status 1A and primary blood type match with the donor~~
~~2~~	~~OPO's DSA~~	~~Adult or pediatric status 1A and secondary blood type match with the donor~~
~~3~~	~~OPO's DSA~~	~~Adult or pediatric status 1B and primary blood type match with the donor~~
~~4~~	~~OPO's DSA~~	~~Adult or pediatric status 1B and secondary blood type match with the donor~~
~~5~~	~~Zone A~~	~~Adult or pediatric status 1A and primary blood type match with the donor~~
~~6~~	~~Zone A~~	~~Adult or pediatric status 1A and secondary blood type match with the donor~~
~~7~~	~~Zone A~~	~~Adult or pediatric status 1B and primary blood type match with the donor~~
~~8~~	~~Zone A~~	~~Adult or pediatric status 1B and secondary blood type match with the donor~~
~~9~~	~~OPO's DSA~~	~~Adult or pediatric status 2 and primary blood type match with the donor~~
~~10~~	~~OPO's DSA~~	~~Adult or pediatric Status 2 and secondary blood type match with the donor~~
~~11~~	~~Zone B~~	~~Adult or pediatric status 1A and primary blood type match with the donor~~
~~12~~	~~Zone B~~	~~Adult or pediatric status 1A and secondary blood type match with the donor~~
~~13~~	~~Zone B~~	~~Adult or pediatric status 1B and primary blood type match with the donor~~
~~14~~	~~Zone B~~	~~Adult or pediatric status 1B and secondary blood type match with the donor~~

15	Zone A	Adult or pediatric status 2 and primary blood type match with the donor
16	Zone A	Adult or pediatric status 2 and secondary blood type match with the donor
17	Zone B	Adult or pediatric status 2 and primary blood type match with the donor
18	Zone B	Adult or pediatric status 2 and secondary blood type match with the donor
19	Zone C	Adult or pediatric status 1A and primary blood type match with the donor
20	Zone C	Adult or pediatric status 1A and secondary blood type match with the donor
21	Zone C	Adult or pediatric status 1B and primary blood type match with the donor
22	Zone C	Adult or pediatric status 1B and secondary blood type match with the donor
23	Zone C	Adult or pediatric status 2 and primary blood type match with the donor
24	Zone C	Adult or pediatric status 2 and secondary blood type match with the donor
25	Zone D	Adult or pediatric status 1A and primary blood type match with the donor
26	Zone D	Adult or pediatric status 1A and secondary blood type match with the donor
27	Zone D	Adult or pediatric status 1B and primary blood type match with the donor
28	Zone D	Adult or pediatric status 1B and secondary blood type match with the donor
29	Zone D	Adult or pediatric status 2 and primary blood type match with the donor
30	Zone D	Adult or Pediatric Status 2 and secondary blood type match with the donor
31	Zone E	Adult or pediatric status 1A and primary blood type match with the donor
32	Zone E	Adult or pediatric status 1A and secondary blood type match with the donor
33	Zone E	Adult or pediatric status 1B and primary blood type match with the donor
34	Zone E	Adult or pediatric status 1B and secondary blood type match with the donor
35	Zone E	Adult or pediatric status 2 and primary

		~~blood type match with the donor~~
~~**36**~~	~~Zone E~~	~~Adult or pediatric status 2 and secondary blood type match with the donor~~

6.5.E Allocation of Hearts from Donors Less Than 18 Years Old

A heart from a pediatric donor will be allocated to a pediatric heart candidate by status and geographical location before being allocated to a candidate at least 18 years old according to *Table 6-9* below.

Table 6-9: Allocation of Hearts from Donors Less Than 18 Years Old

Classification	Candidates that are within the:	And are:
1	OPO's DSA or Zone A	Pediatric status 1A and primary blood type match with the donor
2	OPO's DSA or Zone A	Pediatric status 1A and secondary blood type match with the donor
3	OPO's DSA or Zone A	Adult status 1 and primary blood type match with the donor
4	OPO's DSA or Zone A	Adult status 1 and secondary blood type match with the donor
5	Zone B	Pediatric status 1A and primary blood type match with the donor
6	Zone B	Pediatric status 1A and secondary blood type match with the donor
7	Zone B	Adult status 1 and primary blood type match with the donor
8	Zone B	Adult status 1 and secondary blood type match with the donor
9	OPO's DSA or Zone A	Adult status 2 and primary blood type match with the donor
10	OPO's DSA or Zone A	Adult status 2 and secondary blood type match with the donor
11	Zone B	Adult status 2 and primary blood type match with the donor
12	Zone B	Adult status 2 and secondary blood type match with the donor
13	OPO's DSA	Pediatric status 1B and primary blood type match with the donor
14	OPO's DSA	Pediatric status 1B and secondary blood type match with the donor
15	OPO's DSA	Adult status 3 and primary blood type match with the donor
16	OPO's DSA	Adult status 3 and secondary blood type match with the donor
17	OPO's DSA	Adult status 4 and primary blood type match with the donor

Classification	Candidates that are within the:	And are:
18	OPO's DSA	Adult status 4 and secondary blood type match with the donor
19	Zone A	Pediatric status 1B and primary blood type match with the donor
20	Zone A	Pediatric status 1B and secondary blood type match with the donor
21	Zone A	Adult status 3 and primary blood type match with the donor
22	Zone A	Adult status 3 and secondary blood type match with the donor
23	OPO's DSA	Adult status 5 and primary blood type match with the donor
24	OPO's DSA	Adult status 5 and secondary blood type match with the donor
25	Zone B	Pediatric status 1B and primary blood type match with the donor
26	Zone B	Pediatric status 1B and secondary blood type match with the donor
27	Zone B	Adult status 3 and primary blood type match with the donor
28	Zone B	Adult status 3 and secondary blood type match with the donor
29	OPO's DSA	Pediatric status 2 and primary blood type match with the donor
30	OPO's DSA	Pediatric status 2 and secondary blood type match with the donor
31	OPO's DSA	Adult status 6 and primary blood type match with the donor
32	OPO's DSA	Adult status 6 and secondary blood type match with the donor
33	Zone C	Pediatric status 1A and primary blood type match with the donor
34	Zone C	Pediatric status 1A and secondary blood type match with the donor
35	Zone C	Adult status 1 and primary blood type match with the donor
36	Zone C	Adult status 1 and secondary blood type match with the donor
37	Zone C	Adult status 2 and primary blood type match with the donor
38	Zone C	Adult status 2 and secondary blood type match with the donor
39	Zone C	Pediatric status 1B and primary blood type match with the donor

Classification	Candidates that are within the:	And are:
40	Zone C	Pediatric status 1B and secondary blood type match with the donor
41	Zone C	Adult status 3 and primary blood type match with the donor
42	Zone C	Adult status 3 and secondary blood type match with the donor
43	Zone A	Adult status 4 and primary blood type match with the donor
44	Zone A	Adult status 4 and secondary blood type match with the donor
45	Zone A	Adult status 5 and primary blood type match with the donor
46	Zone A	Adult status 5 and secondary blood type match with the donor
47	Zone A	Pediatric status 2 and primary blood type match with the donor
48	Zone A	Pediatric status 2 and secondary blood type match with the donor
49	Zone A	Adult status 6 and primary blood type match with the donor
50	Zone A	Adult status 6 and secondary blood type match with the donor
51	Zone D	Pediatric status 1A and primary blood type match with the donor
52	Zone D	Pediatric status 1A and secondary blood type match with the donor
53	Zone D	Adult status 1 and primary blood type match with the donor
54	Zone D	Adult status 1 and secondary blood type match with the donor
55	Zone D	Adult status 2 and primary blood type match with the donor
56	Zone D	Adult status 2 and secondary blood type match with the donor
57	Zone D	Pediatric status 1B and primary blood type match with the donor
58	Zone D	Pediatric status 1B and secondary blood type match with the donor
59	Zone D	Adult status 3 and primary blood type match with the donor
60	Zone D	Adult status 3 and secondary blood type match with the donor
61	Zone B	Adult status 4 and primary blood type match with the donor

Classification	Candidates that are within the:	And are:
62	Zone B	Adult status 4 and secondary blood type match with the donor
63	Zone B	Adult status 5 and primary blood type match with the donor
64	Zone B	Adult status 5 and secondary blood type match with the donor
65	Zone B	Pediatric status 2 and primary blood type match with the donor
66	Zone B	Pediatric status 2 and secondary blood type match with the donor
67	Zone B	Adult status 6 and primary blood type match with the donor
68	Zone B	Adult status 6 and secondary blood type match with the donor
69	Zone E	Pediatric status 1A and primary blood type match with the donor
70	Zone E	Pediatric status 1A and secondary blood type match with the donor
71	Zone E	Adult status 1 and primary blood type match with the donor
72	Zone E	Adult status 1 and secondary blood type match with the donor
73	Zone E	Adult status 2 and primary blood type match with the donor
74	Zone E	Adult status 2 and secondary blood type match with the donor
75	Zone E	Pediatric status 1B and primary blood type match with the donor
76	Zone E	Pediatric status 1B and secondary blood type match with the donor
77	Zone E	Adult status 3 and primary blood type match with the donor
78	Zone E	Adult status 3 and secondary blood type match with the donor
79	Zone C	Adult status 4 and primary blood type match with the donor
80	Zone C	Adult status 4 and secondary blood type match with the donor
81	Zone C	Adult status 5 and primary blood type match with the donor
82	Zone C	Adult status 5 and secondary blood type match with the donor
83	Zone C	Pediatric status 2 and primary blood type match with the donor

Classification	Candidates that are within the:	And are:
84	Zone C	Pediatric status 2 and secondary blood type match with the donor
85	Zone C	Adult status 6 and primary blood type match with the donor
86	Zone C	Adult status 6 and secondary blood type match with the donor
87	Zone D	Adult status 4 and primary blood type match with the donor
88	Zone D	Adult status 4 and secondary blood type match with the donor
89	Zone D	Adult status 5 and primary blood type match with the donor
90	Zone D	Adult status 5 and secondary blood type match with the donor
91	Zone D	Pediatric status 2 and primary blood type match with the donor
92	Zone D	Pediatric status 2 and secondary blood type match with the donor
93	Zone D	Adult status 6 and primary blood type match with the donor
94	Zone D	Adult status 6 and secondary blood type match with the donor
95	Zone E	Adult status 4 and primary blood type match with the donor
96	Zone E	Adult status 4 and secondary blood type match with the donor
97	Zone E	Adult status 5 and primary blood type match with the donor
98	Zone E	Adult status 5 and secondary blood type match with the donor
99	Zone E	Pediatric status 2 and primary blood type match with the donor
100	Zone E	Pediatric status 2 and secondary blood type match with the donor
101	Zone E	Adult status 6 and primary blood type match with the donor
102	Zone E	Adult status 6 and secondary blood type match with the donor

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~
~~1~~	~~OPO's DSA or Zone A~~	~~Pediatric status 1A and primary blood type match with the donor~~

Classification	Candidates that are within the:	And are:
2	OPO's DSA or Zone A	Pediatric status 1A and secondary blood type match with the donor
3	OPO's DSA	Adult status 1A and primary blood type match with the donor
4	OPO's DSA	Adult status 1A and secondary blood type match with the donor
5	OPO's DSA or Zone A	Pediatric status 1B and primary blood type match with the donor
6	OPO's DSA or Zone A	Pediatric Status 1B and secondary blood type match with the donor
7	OPO's DSA	Adult Status 1B and primary blood type match with the donor
8	OPO's DSA	Adult Status 1B and secondary blood type match with the donor
9	Zone A	Adult Status 1A and primary blood type match with the donor
10	Zone A	Adult Status 1A and secondary blood type match with the donor
11	Zone A	Adult Status 1B and primary blood type match with the donor
12	Zone A	Adult Status 1B and secondary blood type match with the donor
13	OPO's DSA	Pediatric status 2 and primary blood type match with the donor
14	OPO's DSA	Pediatric status 2 and secondary blood type match with the donor
15	OPO's DSA	Adult status 2 and primary blood type match with the donor
16	OPO's DSA	Adult status 2 and secondary blood type match with the donor
17	Zone B	Pediatric status 1A and primary blood type match with the donor
18	Zone B	Pediatric status 1A and secondary blood type match with the donor
19	Zone B	Adult status 1A and primary blood type match with the donor
20	Zone B	Adult status 1A and secondary blood type match with the donor
21	Zone B	Pediatric status 1B and primary blood type match with the donor
22	Zone B	Pediatric status 1B, secondary blood type match with the donor
23	Zone B	Adult status 1B and primary blood type match with the donor

Classification	Candidates that are within the:	And are:
24	Zone B	Adult status 1B and secondary blood type match with the donor
25	Zone A	Pediatric status 2 and primary blood type match with the donor
26	Zone A	Pediatric status 2 and secondary blood type match with the donor
27	Zone A	Adult status 2 and primary blood type match with the donor
28	Zone A	Adult status 2 and secondary blood type match with the donor
29	Zone B	Pediatric status 2, primary blood type match with the donor
30	Zone B	Pediatric status 2 and secondary blood type match with the donor
31	Zone B	Adult status 2 and primary blood type match with the donor
32	Zone B	Adult status 2 and secondary blood type match with the donor
33	Zone C	Pediatric status 1A and primary blood type match with the donor
34	Zone C	Pediatric status 1A and secondary blood type match with the donor
35	Zone C	Adult status 1A and primary blood type match with the donor
36	Zone C	Adult status 1A and secondary blood type match with the donor
37	Zone C	Pediatric status 1B and primary blood type match with the donor
38	Zone C	Pediatric status 1B and secondary blood type match with the donor
39	Zone C	Adult status 1B and primary blood type match with the donor
40	Zone C	Adult status 1B and secondary blood type match with the donor
41	Zone C	Pediatric status 2 and primary blood type match with the donor
42	Zone C	Pediatric status 2 and secondary blood type match with the donor
43	Zone C	Adult status 2 and primary blood type match with the donor
44	Zone C	Adult status 2 and secondary blood type match with the donor
45	Zone D	Pediatric status 1A and primary blood type match with the donor

Classification	Candidates that are within the:	And are:
46	Zone D	Pediatric status 1A and secondary blood type match with the donor
47	Zone D	Adult status 1A and primary blood type match with the donor
48	Zone D	Adult status 1A and secondary blood type match with the donor
49	Zone D	Pediatric status 1B and primary blood type match with the donor
50	Zone D	Pediatric status 1B and secondary blood type match with the donor
51	Zone D	Adult status 1B and primary blood type match with the donor
52	Zone D	Adult status 1B and secondary blood type match with the donor
53	Zone D	Pediatric status 2 and primary blood type match with the donor
54	Zone D	Pediatric status 2 and secondary blood type match with the donor
55	Zone D	Adult status 2 and primary blood type match with the donor
56	Zone D	Adult status 2 and secondary blood type match with the donor
57	Zone E	Pediatric status 1A and primary blood type match with the donor
58	Zone E	Pediatric status 1A and secondary blood type match with the donor
59	Zone E	Adult status 1A and primary blood type match with the donor
60	Zone E	Adult status 1A and secondary blood type match with the donor
61	Zone E	Pediatric status 1B and primary blood type match with the donor
62	Zone E	Pediatric status 1B and secondary blood type match with the donor
63	Zone E	Adult status 1B and primary blood type match with the donor
64	Zone E	Adult status 1B and secondary blood type match with the donor
65	Zone E	Pediatric status 2 and primary blood type match with the donor
66	Zone E	Pediatric status 2 and secondary blood type match with the donor
67	Zone E	Adult status 2 and primary blood type match with the donor

~~Classification~~	~~Candidates that are within the:~~	~~And are:~~
~~68~~	~~Zone E~~	~~Adult status 2 and secondary blood type match with the donor~~

6.5.F Allocation of Heart-Lungs

When a heart-lung potential transplant recipient (PTR) ~~candidate~~ is offered ~~allocated~~ a heart, the lung from the same deceased donor must be offered ~~allocated~~ to the heart-lung PTR ~~candidate~~.

When a heart-lung ~~candidate~~ PTR is ~~allocated~~ offered a lung, the heart from the same deceased donor must be offered ~~may only be allocated~~ to the heart-lung PTR according to *Table 6-10* below ~~candidate if no suitable Status 1A isolated heart candidates are eligible to receive the heart~~.

Table 6-10: Allocation of Heart-Lungs If PTR is Offered the Lung

When a heart-lung PTR in this geographic area is offered a lung:	The heart from the same deceased donor must only be offered to the heart-lung PTR after the heart has been offered to all	Within this geographic area:
DSA, Zone A or Zone B	Pediatric status 1A and Adult status 1 or status 2 isolated heart PTRs	DSA, Zone A or Zone B
Zone C	Pediatric status 1A and Adult status 1 or status 2 isolated heart PTRs	Zone C
Zone D	Pediatric status 1A and Adult status 1 or status 2 isolated heart PTRs	Zone D
Zone E	Pediatric status 1A and Adult status 1 or status 2 isolated heart PTRs	Zone E

The blood type matching requirements described in *Policy 6.5.A: Allocation of Hearts by Blood Type* apply to heart-lung candidates when the candidates appear on the heart match run. The blood type matching requirements in *Policy 10.4.B: Allocation of Lungs by Blood Type* applies to heart-lung candidates when the candidates appear on the lung match run.

3.7.B Required Expedited Modifications of Waiting Time

An application for waiting time modifications must follow the procedures for expedited modifications of waiting time if it meets *any* of the following criteria according to *Table 3-5* below:

Table 3-5: Applications Requiring Expedited Modifications of Waiting Time

When:	And the candidate is registered for:	And the transplant program is requesting reinstatement of waiting time including:
An error occurred in removing the candidate's waiting list record	The same organ	Time accrued under the previous registration and any time lost by the error.

When:	And the candidate is registered for:	And the transplant program is requesting reinstatement of waiting time including:
An error occurred in registering, modifying, or renewing the candidate's waiting list record	Status 1 liver, pediatric status 1A heart, adult status 1, 2, 3, or 4 heart, or priority 1 pediatric lung	Any time lost by the error.
The candidate was removed from the waiting list for medical reasons, other than receiving a transplant	The same organ with the same diagnosis	Time accrued under the previous registration without the time interval when the candidate was removed from the waiting list.
An islet recipient has re-registered on the islet waiting list	An islet infusion	Any previously accrued waiting time according to *Policy 11.3.C: Islet Waiting Time Criteria*.
The candidate needs a second organ	Heart, liver, or lung	Modified waiting time for the second organ that includes the waiting time accrued for the first organ.
The candidate needs a second organ, routine alternative therapies are not possible, and the other transplant programs within the OPO and the OPO itself agree to the modified waiting time	Kidney, pancreas, or intestine	Modified waiting time for the second organ that includes the waiting time for the first organ.

Additionally, applications must meet any additional requirements outlined in the organ-specific allocation policies. If an application does not comply with the requirements of *Policy 3.7: Waiting Time Modifications*, then the OPTN Contractor will not implement the requested waiting time modifications or forward the application for review.

Applications eligible for expedited modifications of waiting time must use the following process:

1. Upon receipt of a complete application, including the name and signature of the candidate's physician or surgeon, the OPTN Contractor will implement the waiting time modification.
2. The OPTN Contractor will report the modification, without person-identified data, to the relevant organ-specific Committee.
3. The Committee will report the modification, without person-identified data, to the Board of Directors.

#

Appendix A: Qualifying Devices and Classifications

Device Name	Dischargeable?	ACS	LVAD	RVAD	BiVAD
Abiomed AB5000	N	Y	Y	Y	Y
Abiomed BVS 5000	N	Y	Y	Y	Y
Abiomed Impella 2.5	N	Y	Y	N	N
Abiomed Impella 5.0	N	Y	Y	N	N
Abiomed Impella CP	N	Y	Y	N	N
Abiomed Impella LD	N	Y	Y	N	N
Abiomed Impella RP	N	Y	N	Y	N
Berlin Heart EXCOR	N	Y	Y	Y	Y
Biomedicus	N	Y	Y	Y	Y
Cardiac Assist Tandem Heart	N	Y	Y	Y	Y
Cardiac Assist PROTEK Duo	N	Y	N	Y	N
CentriMag (Thoratec/Levitronix)	N	Y	Y	Y	Y
Evaheart	Y	N	Y	N	N
Heartmate II	Y	N	Y	N	N
Heartmate III	Y	N	Y	Y	Y
Heartmate PHP	N	Y	Y	N	N
Heartmate XVE	Y	N	Y	N	N
Heartware HVAD	Y	N	Y	Y	Y
Heartware MVAD	Y	N	Y	Y	Y
Jarvik 2000	Y	N	Y	Y	Y
Maquet Jostra Rotaflow	N	Y	Y	Y	Y
PediMag (Thoratec/Levitronix)	N	Y	Y	Y	Y
Reliant HeartAssist 5	Y	N	Y	N	N
Revolution	N	Y	Y	Y	Y
Terumo DuraHeart	Y	N	Y	N	N
Thoratec/St. Jude IVAD	Y	Y	Y	Y	Y
Thoratec/St. Jude PVAD	Y	Y	Y	Y	Y
Toyobo	N	Y	Y	Y	Y

Appendix B: Qualifying Congenital Heart Disease Diagnoses

1. Double Outlet Right Ventricle
2. Atrial isomerism / Heterotaxy
3. Atrioventricular Septal Defect
4. Congenitally Corrected Transposition (L-TGA)
5. Ebstein's Anomaly
6. Hypoplastic Left Heart Syndrome
7. Other left Heart Valvar/Structural Hypoplasia
8. Pulmonary Atresia with Intact Ventricular Septum
9. Single Ventricle
10. Tetralogy of Fallot
11. Transposition of the Great Arteries
12. Truncus Arteriosus
13. Ventricular Septal Defect(s)
14. *Other _____

Exhibit A

Analysis Report

Data Request from the Heart Subcommittee of the OPTN Thoracic Organ Transplantation Committee

Meeting: June 11, 2015

This report was provided by the SRTR to HRSA in support of ongoing policy consideration by the OPTN Thoracic Organ Transplantation Committee. The analysis described herein was conducted at the specific request of the OPTN Committee and does not represent a full or final analysis related to this issue.

Prepared by
Monica Colvin, MD, MS; Melissa Skeans, MS; Joshua Pyke, PhD; Charlotte Bolch, MS; Jessica Zeglin, MPH; Xinyue Wang, BS, BA

Data Request ID#: HR2015_01

Timeline

Request made	June 25, 2015
Analysis plan submitted	July 9, 2015
Draft analysis submitted	September 18, 2015
Final analysis submitted	October 26, 2015
Next committee meeting	October 29, 2015

Contents

914 SOUTH 8TH STREET SUITE S2.100 MINNEAPOLIS, MN 55404 1.877.970.SRTR 612.347.SRTR WWW.SRTR.ORG

OPTN Committee Request

Background

The Heart Subcommittee has been working on revisions to heart allocation policy for adult candidates. Following a considerable amount of effort, the Subcommittee developed a set of six (active) prioritization tiers. Subsequently, the Subcommittee has focused its energy on geographic ordering. Subcommittee members developed underlying principles, and then translated these into specific orderings for all of the patient classifications. As some of these principles reflected competing goals, the Subcommittee developed a set of four different geographic orderings to be simulated.

Program goal or committee annual work item addressed

Modify Policy 3.7.3 (Adult Candidate Status) to Better Address the Medical Urgency of Candidates Implanted with Mechanical Circulatory Support Devices (MCSD)

Data request

Simulate the four sets of allocation rules (Appendix A, Table A-1 through Table A-4). The results of the four requested simulations will be provided in addition to a simulation of the existing allocation system and tiers, for comparison purposes.

On 9/24/2015, SRTR presented selected TSAM data to the Heart Subcommittee, in response to the request to model several different sets of allocation rules that offered broader sharing to the most acutely ill candidates. That discussion generated a request to see more data by tier-defining sub-criteria. In some cases, sub-criteria groups are so small, and rate ranges are so large, that rates estimates are not very stable. For tiers 1-4, we provide event counts for all sub-criteria, and rates where counts are sufficiently large to compute them. Since the discussion was limited to the Sh 1/2A and Sh 1/2B simulations, we limited the data to simulations of current rules, allocation by tier, Sh 1/2A, and Sh 1/2B.

914 SOUTH 8TH STREET SUITE S2.100 MINNEAPOLIS, MN 55404 1.877.970.SRTR 612.347.SRTR WWW.SRTR.ORG

Study population

The simulation included transplant candidates listed on the heart and heart-lung waiting lists on June 30, 2009, and candidates added to those waiting lists between July 1, 2009, and June 30, 2011, as well as all hearts and lungs offered for transplant between July 1, 2009, and June 30, 2011. However, results for lung transplant candidates are not included in the report.

Analytical approach

We applied both the current (as of July 1, 2015) allocation rules (status 1A, 1B, and 2) and conceptualized tier allocation rules (tiers 1-6) as well as the four sets of requested allocation rules to the study population and compared the results of these 6 scenarios. Each simulation was repeated 10 times with different orderings of organ arrivals and random number seeds to provide a measure of variability. The average, minimum, and maximum of the outcomes below were calculated.

1. Candidate counts
2. Counts of deaths on the waiting list
3. Waitlist mortality rates, deaths per person-years of observation
4. Counts of removals from the waiting list
5. Transplant counts
6. Transplant rates (transplants per person-years of observation)
7. Counts of posttransplant deaths and posttransplant mortality rates (deaths per person-year of observation) at 1 and 2 years posttransplant

Each of the proposed metrics was computed overall and by age group, race/ethnicity, diagnosis group, sex, blood type, and severity tier. Additionally, transplant counts are shown by zone and distance. Detailed data tables are included in Appendix B. These tables show waitlist and posttransplant outcomes for current rules vs. all tiers and sharing simulations, and observed data. Observed results occurred in the cohort population outside the simulation. For simulated results, each table presented in Appendix B shows the average, minimum, and maximum values for each metric across the ten runs of each set of simulated rules.

Summary

- Simulations of allocation by tiers and broader geographic sharing rules prioritized allocation to tiers 1 and 2 compared with current rules.
- Simulations of broader geographic sharing rules resulted in slightly lower overall transplant rates, lower waitlist mortality rates, and similar posttransplant mortality rates compared with simulated allocation according to current rules. For the most part, the four broader sharing rules behaved similarly to each other regarding transplant rates, waitlist mortality, and posttransplant mortality.
- Simulations of all broader sharing rules resulted in:
    - Vastly higher transplant rates for tier 1 and 2 candidates compared with current rules, and 2- to 3-fold increases in transplant rates for tier 1 and 2 candidates compared with allocation by tiers within current geographic definitions, without marked increases in waitlist or posttransplant mortality.
    - Similar or higher transplant rates among tier 3 candidates, lower transplant rates among tier 4 candidates, and similar transplant rates among tier 5 and 6 candidates, compared with current rules, without marked increases in waitlist or posttransplant mortality.
    - Higher transplant rates among status 1A adults and lower rates among status 1B adults compared with current rules, with a trend toward lower waitlist mortality among status 1A and

inactive candidates. Sharing may have resulted in higher posttransplant mortality among status 1A adults, though the simulation results overlap.

- Fewer local transplants and more zone A and B transplants than under current rules. Transplants in zones C, D, and E were rare in all simulations.
- Higher transplant rates among status 1A children and lower rates among status 1B children (for 2 of the 4 broader sharing rules) compared with current rules, without increases in waitlist or posttransplant mortality.

- Among inactive candidates, three sets of broader sharing rules resulted in modest improvements in waitlist mortality compared with allocation by tiers.
- Broader sharing simulations resulted in some trends toward lower transplant rates among candidates aged 35-49 and 50-64 years, though ranges of simulations overlapped. Waitlist mortality was lower for these two age groups with broader sharing, and posttransplant mortality was similar across all simulations and all age groups.
- Among children, broader sharing simulations indicated decreased transplant rates for candidates aged 0-5 years, a possible increase in rates for candidates aged 6-11 years, and increased rates for candidates aged 12-17 years. Waitlist and posttransplant mortality were similar to current rules for all sharing rules and pediatric age groups.
- Though some differences occurred, we did not detect systematic disparity in access to transplant by race, primary diagnosis, blood type, or sex in any simulation. Exceptions:
  - Broader sharing may have resulted in lower transplant rates for black candidates, but also lower waitlist mortality rates compared with current rules.
  - Broader sharing may have resulted in lower transplant rates for candidates with coronary artery disease and cardiomyopathy, but also lower waitlist mortality rates compared with current rules. With broader sharing, transplant rates were higher and waitlist mortality rates were lower for candidates with other/unknown causes of heart failure.

914 SOUTH 8TH STREET SUITE S2.100 MINNEAPOLIS, MN 55404 1.877.970.SRTR 612.347.SRTR WWW.SRTR.ORG

Tiers and allocation orderings

The Heart Subcommittee defined tiers 1-7 primarily using criteria that define status 1A, status 1B, and status 2 under the current allocation system. For the most part, status 1A candidates were classified into tiers 1-3, status 1B candidates were classified as tier 4, and status 2 candidates were classified into tiers 5 and 6. To avoid confusion, "status 1A," "status 1B," and "status 2" in this report refer to urgency status under the current allocation system. We use tier number to refer to data by status tier. See Table 1 to cross reference tier number with the most closely related status group, and Table 2 for a detailed description of each tier.

Table 1. Overview of tier definitions matched to current status

Tier Number	Status
1	Status 1A
2	Status 1A
3	Status 1A
4	Status 1B, with a small group of status 2
5	ACO listings, status 2
6	Status 2
7	Inactive

914 SOUTH 8TH STREET SUITE S2.100 MINNEAPOLIS, MN 55404 1.877.970.SRTR 612.347.SRTR WWW.SRTR.ORG

Table 2. Detailed tier definition

Tier	Proposed Tiers	Corresponding Criteria in OPTN/UNOS Policy 3.7.3 as of September 1, 2014
1	i. ECMO ii. Mechanical ventilation iii. Non-dischargeable (surgically implanted) VAD iv. Mechanical circulatory support with life-threatening ventricular arrhythmia	i. Status 1A(a)(iv) ii. Status 1A(c) iii. Subset of status 1A(a)(i) and subset of status 1B(aa) iv. Status 1A(b)(iv)
2	i. Intra-aortic balloon pump ii. Ventricular tachycardia/ventricular fibrillation, mechanical support not required iii. Mechanical circulatory support with device malfunction/mechanical failure iv. Total artificial heart v. Dischargeable BiVAD or RVAD vi. Acute circulatory support	i. Status 1A(a)(iii) ii. Subset of status 1A exceptions iii. Status 1A(b)(iii) iv. Status 1A(a)(ii) v. Subset of status 1A(a)(i) and subset of status 1B(aa)
3	i. Dischargeable LVAD for up to 30 days ii. Status 1A exception iii. Multiple inotropes or single high-dose inotropes with continuous hemodynamic monitoring iv. Mechanical circulatory support with device infection v. Mechanical circulatory support with thromboembolism vi. Mechanical circulatory support with device-related complications other than infection, thromboembolism, device malfunction/mechanical failure or life-threatening ventricular arrhythmia	i. Subset of status 1A(a)(i) ii. Status 1A(e) iii. Status 1A(d) iv. Status 1A(b)(ii) v. Status 1A(b)(i) vi. Status 1A(b)(v)
4	i. Diagnosis of congenital heart disease (CHD) with: a. Unrepaired/incompletely repaired complex CHD, usually with cyanosis b. Repaired CHD with two ventricles (e.g., TOF, TOGV) c. Single ventricle repaired with Fontan or modifications ii. Diagnosis of ischemic heart disease with intractable angina iii. Diagnosis of hypertrophic cardiomyopathy iv. Diagnosis of restrictive cardiomyopathy v. Diagnosis of amyloidosis vi. Stable LVAD candidates after 30 days vii. Inotropes without hemodynamic monitoring viii. Retransplant ix. Status 1B exceptions	i. NA ii. NA iii. NA iv. NA v. NA vi. Subset of status 1B(aa) vii. Status 1B(bb) viii. NA ix. Status 1B = exception
5	Approved combined organ transplants: heart-lung; heart-liver; heart-kidney	Not applicable
6	All remaining active candidates	Status 2
7	Inactive/unable to undergo transplant	Inactive

Allocation rules that were simulated in this analysis are shown in detail in Appendix A, Table A-1 to Table A-4. Table 3 provides a brief description of each set of simulated allocation rules and how it differs from the others.

914 SOUTH 8TH STREET SUITE S2.100 MINNEAPOLIS, MN 55404 1.877.970.SRTR 612.347.SRTR WWW.SRTR.ORG

Table 3. Descriptions of allocation orderings

Simulation Name	Description
CurRule	Current allocation rules by status 1A, 1B, and 2, as of July 1, 2015, and current geographic allocation rules as of July 1, 2015
By tier	Candidates classified by tier rather than status. Organs are offered to most severe tiers first, but generally follow ordering of current rules to allow for direct comparison. Uses an approximation to current geographic allocation rules as of July 1, 2015.
Sh 1/2A	Share to zone B for tier 1, then zone B to tier 2 before offers are made to tier 3.
Sh 1/2B	Similar to Sh 1/2A, but with sharing to zone A among tier 3 candidates before tier 4 offers are made.
Sh All	No local preference for any tier, with sharing to zone B for tier 1, then tier 2, and sharing to zone A for tier 3, then tier 4.
TierPr	No combined zones. Offers made sequentially locally, to zone A, then zone B for tier 1, locally, to zone A, then zone B for tier 2.

Results

Cohort description

The total TSAM cohort included 9725 heart and 188 heart-lung candidates listed for at least 1 day during the period from July 1, 2009, through June 30, 2011. Eighty candidates listed during the TSAM time frame were excluded from the TSAM input files for a variety of technical reasons.

Characteristics of candidates in the cohort are given in Table 4. Distributions are shown for all candidates and for candidates active on the waiting list for at least 1 day during the cohort period. Since offers are not made to inactive candidates, the effective TSAM candidate cohort included only candidates active for 1 or more days during the period (n = 9026). Most candidates were adults (87%). Fewer than 2% were listed for heart-lung transplant. Child candidates were not assigned a tier and were allocated organs according to pediatric status 1A, 1B, and 2 in simulations.

Characteristics of the TSAM cohort at the time of observed transplant are given in Table 5. These candidates in the TSAM cohort underwent transplant in real life. They may or may not appear in a given simulation's recipient distribution, but they are representative. Most recipients were adult (84%), male (71%), and white (67%). Cardiomyopathy was a primary diagnosis for more than half of recipients (52%). Nearly 60% underwent transplant at status 1A. Seventy recipients (1.5%) underwent transplant at tier 1, the most severe designation, and 397 (8.6%) underwent transplant at tier 2.

The majority of transplants in the TSAM cohort resulted from local offers (53%), reflecting the current allocation system's prioritization. Less than 1% of transplants resulted from zone C and D offers combined, and none resulted from zone E offers. Donor-recipient pairs were within 50 miles of each other for 34% of transplants, and 500 miles apart or greater for 8%.

Table 4. Characteristics of heart and heart-lung candidates in the TSAM cohort, July 1, 2009-June 30, 2011

Characteristic	Level	All Candidates N	All Candidates %	Active Candidates N	Active Candidates %
Age	< 1	452	4.6	398	4.4
	1-5	318	3.2	276	3.1
	6-11	219	2.2	205	2.3
	12-17	374	3.8	340	3.8
	18-34	1051	10.6	907	10.1
	35-49	2032	20.5	1823	20.2
	50-64	4345	43.8	4017	44.5
	≥ 65	1122	11.3	1060	11.7
Sex	Male	7082	71.4	6477	71.8
	Female	2831	28.6	2549	28.2
Race	White	6701	67.6	6082	67.4
	Black	2009	20.3	1842	20.4
	Hispanic	866	8.7	785	8.7
	Asian	250	2.5	237	2.6
	Other/unknown	87	0.9	80	0.9
Blood group	A	3605	36.4	3291	36.5
	AB	1170	11.8	1070	11.9
	B	364	3.7	345	3.8
	O	4774	48.2	4320	47.9
Diagnosis group	Coronary artery disease	3248	32.8	2968	32.9
	Cardiomyopathy	4934	49.8	4491	49.8
	Congenital	992	10.0	898	10.0
	Other/unknown	739	7.5	669	7.4
Organ type	Heart	9725	98.1	8885	98.4
	Heart-lung	188	1.9	141	1.6
Initial status*	1A	2195	22.1	2195	24.3
	1B	3062	30.9	3062	33.9
	2	3330	33.6	3330	36.9
	Inactive	1326	13.4	439	4.9
Final status*	1A	3214	32.4	3214	35.6
	1B	2685	27.1	2685	29.8
	2	1657	16.7	1657	18.4
	Inactive	2357	23.8	1470	16.3
Initial tier*	1	111	1.1	111	1.2
	2	379	3.8	379	4.2
	3	931	9.4	931	10.3
	4	3350	33.8	3350	37.1
	5	158	1.6	158	1.8
	6	2471	24.9	2471	27.4
	7	1150	11.6	407	4.5
	Age < 18, n/a	1363	13.8	1219	13.5
Final tier*	1	100	1.0	100	1.1
	2	478	4.8	478	5.3
	3	1878	18.9	1878	20.8
	4	2763	27.9	2763	30.6
	5	97	1.0	97	1.07
	6	1207	12.2	1207	13.37
	7	2027	20.5	1284	14.23
	Age < 18, n/a	1363	13.8	1219	13.51
All candidates		*9913*	*100.0*	*9026*	*100.0*

*Initial status and tier were the values on July 1, 2009, for candidates already listed on that date, and the values at listing for candidates first listed after that date. Final status and tier were the values on June 30, 2011, for candidates still listed on that date, and the values at removal for candidates removed earlier due to transplant, death, or de-listing.

Table 5. Characteristics of observed heart and heart-lung recipients, July 1, 2009-June 30, 2011

Characteristic	Level	N	%
Age	< 1	224	4.8
	1-5	159	3.4
	6-11	132	2.9
	12-17	219	4.7
	18-34	441	9.5
	35-49	877	19.0
	50-64	2027	43.8
	≥ 65	550	11.9
Sex	Male	3308	71.5
	Female	1321	28.5
Race	White	3094	66.8
	Black	917	19.8
	Hispanic	419	9.1
	Asian	155	3.4
	Other/unknown	44	1.0
Blood group	A	1870	40.4
	AB	651	14.1
	B	261	5.6
	O	1847	39.9
Diagnosis group	Coronary artery disease	1472	31.8
	Cardiomyopathy	2425	52.4
	Congenital	415	9.0
	Other/unknown	317	6.9
Organ type	Heart	4567	98.7
	Heart-lung	62	1.3
Status at transplant	1A	2737	59.1
	1B	1542	33.3
	2	350	7.6
Tier at transplant	1	70	1.5
	2	397	8.6
	3	1666	36.0
	4	1504	32.5
	5	30	0.7
	6	228	4.9
	Age < 18, n/a	734	15.9
Zone	Local	2442	52.8
	Zone A	1829	39.5
	Zone B	320	6.9
	Zone C	35	0.8
	Zone D	3	0.1
	Zone E	0	0.0
Distance	< 50 miles	1557	33.6
	50-< 100 miles	580	12.5
	100-< 250 miles	885	19.1
	250-< 500 miles	1235	26.7
	≥ 500 miles	372	8.0
All recipients		4629	100.0

Overall outcomes

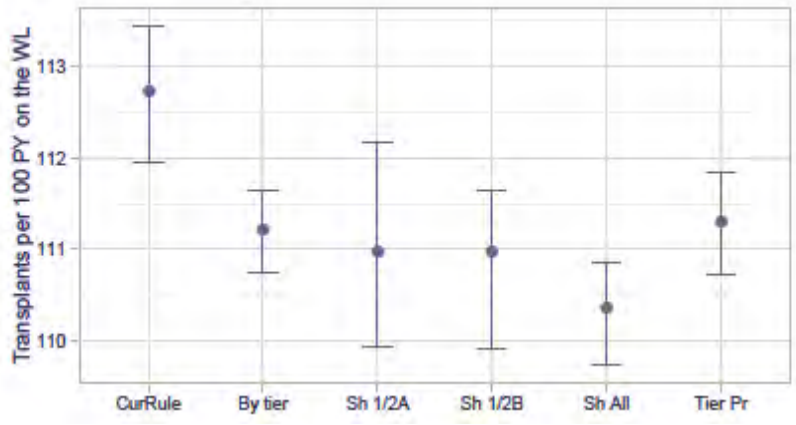
Table B-1 summarizes overall waitlist and posttransplant outcomes for current rules vs. all tiers and sharing simulations, and observed data. Observed results occurred in the cohort population outside the simulation. For simulated results, the table shows average, minimum, and maximum values for each metric across the ten runs of each set of simulated rules.

Overall, the current rules simulation generated the largest number of transplants and the highest transplant rates, but also the highest waitlist death counts, waitlist mortality rates, and removal counts. Overall 1-year and 2-year posttransplant mortality rates were similar across all simulations, though the raw numbers of deaths by 2 years posttransplant were lower for current rules than for other simulations.

Similarities and differences between current rules and other geographic orderings are shown below, including: transplant rates (Figure 1), waitlist mortality rates (Figure 2), 1-year posttransplant mortality rates (Figure 3), and 2-year posttransplant mortality rates (Figure 4). Broader geographic sharing to tier 1 and 2 candidates resulted in lower overall mortality rates than allocation by tier alone, though ranges across simulation iterations generally overlapped for the four sets of sharing rules (Figure 2).

One- and two-year posttransplant mortality rates are based on predicted death dates generated by posttransplant mortality models. Posttransplant mortality trended higher for all tier simulations compared with current rules, but generally the ranges of the simulations overlapped, suggesting that the variability across simulations within a rule was greater than the differences between rules.

Figure 1. Overall transplant rates by simulations



Note that in Figure 1 and in all subsequent figures with minimum/maximum bars (which look like error bars), the interval shown is the range observed over 10 iterations of the simulation, not 95% confidence limits. We generally say that the simulations performed similarly when their ranges overlapped, but this conclusion of similarity is not based on statistical testing. Since each of the 10 iterations within a simulation use the same group of candidates, the 10 iterations are not independent.

Figure 2. Overall waitlist mortality rates by simulation

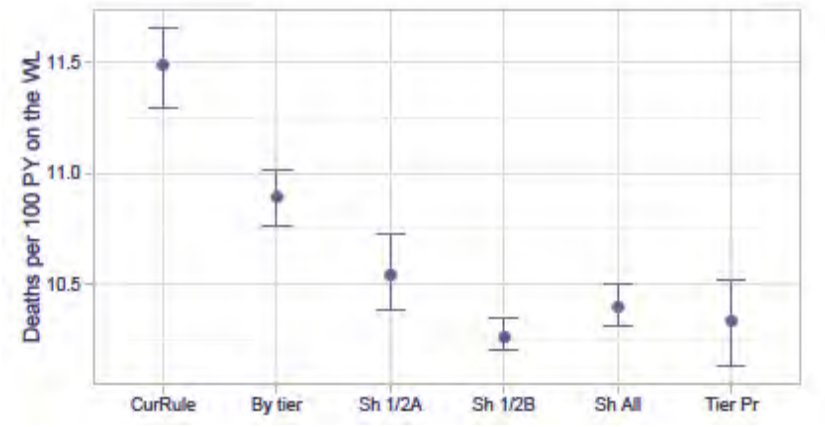


Figure 3. Overall 1-year posttransplant mortality rates by simulation

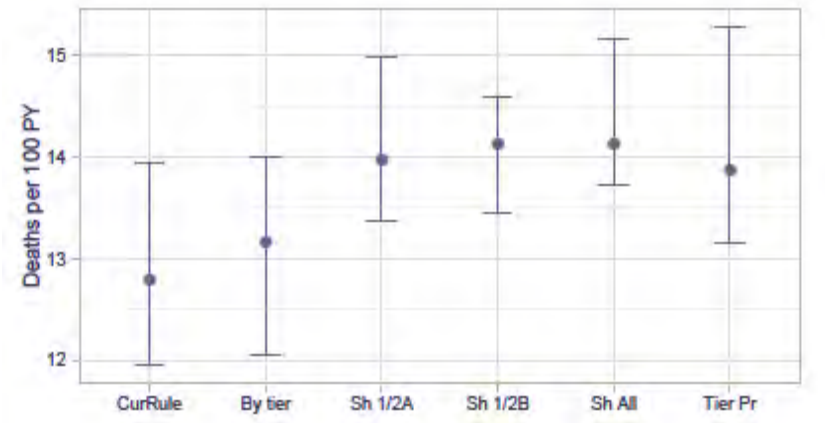
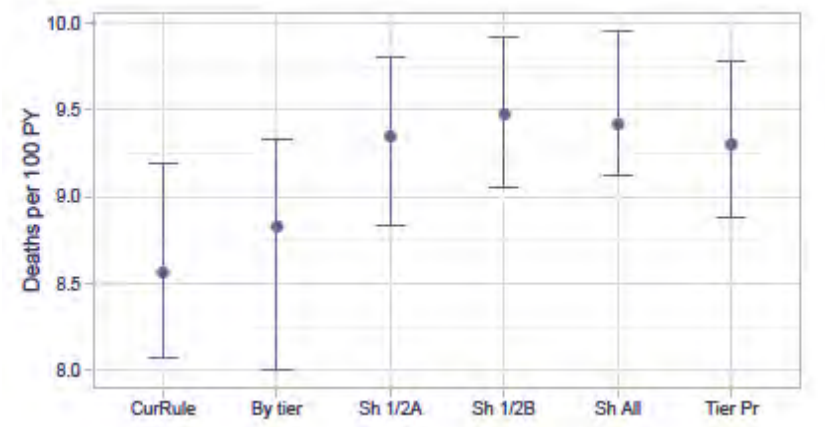


Figure 4. Overall 2-year posttransplant mortality rates by simulation



Outcomes by tier and status, adult candidates and recipients

To more directly compare outcomes by tier and by status, we separated outcomes for adults and for children. Tiers as severity categories were defined for adult candidates, using clinical variables that apply only to adults under current policy.

Detailed waitlist and posttransplant outcomes by simulation and tier are given in Table B-2.

Figure 5 shows transplant rates by simulation and tier. This figure was split into two graphs with different y-axis limits to allow differences across simulations in tiers 4-6 to be visible. The prior data request (DRID HR2014_05) showed that ordering candidates by tier but retaining the current geographic offer order resulted in large increases in transplant rates for the most severe candidates, those in tiers 1 and 2, compared with the current status-based allocation system. In this updated analysis, broader geographic sharing of organs more than doubled the by-tier transplant rates in tiers 1 and 2. The number of tier 1 and 2 candidates was small, and ranges of the transplant rates were wide, but the transplant advantage of broader sharing to these groups is clear. Among tier 1 candidates, transplant rates increased from 615 transplants per 100 patient-years under current rules to 3044 under allocation by tiers, to 7672-7999 under the four broader sharing rules. Among tier 2 candidates, transplant rates increased from 589 transplants per 100 patient-years under current rules to 2363 under allocation by tiers, to 5647-5996 under the four broader sharing rules. The large increase in simulated transplant rates in tiers 1 and 2 was due to both an increase in the number of transplants and decreased waiting time.

Overall, broader sharing rules resulted in higher transplant rates for tier 3 candidates than current rules, and in transplant rates for tier 3 candidates similar to rates under allocation by tier rules. However, in the Sh 1/2A simulation, transplant rates among tier 3 candidates were lower than under current rules and allocation by tiers. This is because the Sh 1/2A rules call for less tier 3 sharing than either current rules or allocation by tiers (Table A-1 and Table A-3).

Transplant rates among tier 4 candidates were lower with broader sharing than under current rules, but these rates differed between broader sharing scenarios. Transplant rates were higher for tier 5 candidates under broader sharing than under allocation by tiers, and rates for tier 6 candidate were lower than under current rules under some sharing rules but higher under others.

Figure 6 shows waitlist mortality rates by tier. As before, tier 1 mortality was higher than for other tiers, but similar across simulations, similar to current rules, and based on low death counts. Fewer than 10 tier 1 candidates died waiting in each of the broader sharing simulations, and 11 tier 1 candidates died in the tiers simulation without broader sharing (Table B-2). Among tier 2-6 candidates, waitlist mortality was similar across simulations. Among inactive candidates, waitlist mortality was lower for all broader sharing simulations except Share 1/2A. A possible explanation of decline in waitlist mortality among inactive candidates is that increased access to transplant at tiers 1 and 2 increased the number of transplants in these groups, and removed candidates from the list before inactivation. Fewer inactive candidates remained listed, so fewer remained at risk for waitlist mortality. Reduced waitlist mortality among inactive candidates was the likeliest driver of reductions in overall waitlist morality.

914 SOUTH 8TH STREET SUITE S2.100 MINNEAPOLIS, MN 55404 1.877.970.SRTR 612.347.SRTR WWW.SRTR.ORG