

# Modifications to the Adult Heart Allocation System

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### **Broader Distribution**

**1. Do you anticipate increased waitlist mortality in those zones that may not have a very productive OPO or access to a higher volume OPO within 500 miles?**

Compared to current policy, we expect lower waitlist mortality among candidates at high status because they will have access to hearts from a wider geographic area. If candidates do not currently have access to a productive OPO, one would not expect waitlist mortality to increase when they (potentially) gain access to additional donors within 500 miles in other OPOs. The OPTN is committed to contributing to efforts that will improve OPO performance.

**2. With a wider area for organ allocation under the new system, will this result in an increase in the number of programs doing a small number of transplants?**

Because of the proposal for broader distribution, transplant programs may not see a decrease in the number of candidates transplanted, but may notice a difference in which candidates are being transplanted. The proposal aims to transplant more urgent candidates quicker, so candidates that are less urgent will get offers, but may have to wait longer than the candidates in proposed statuses 1 and 2.

### **Data**

**1. In general are there time frames for the necessary testing, such as labs, hemodynamics, sensitization data, etc.?**

There is no general answer to this question. For data related to status justifications, it will depend on the status for which the candidate qualifies. For the risk stratification data, the categories are specific about whether they require most recent or whether they require current data, however current isn't meant to *require* a test, it's just meant to capture a snapshot of the candidate currently. If "most recent," then that's exactly what is meant: most recent isn't meant to imply any sort of time frame besides just capturing the most recent time that candidate was tested.

**2. If a transplant program notices that it made an error on a status justification form it has already submitted, can that form be edited?**

No. Once a form has been submitted it cannot be edited by the transplant program or by UNOS staff. The transplant program will need to submit a new form with correct data.

**3. When is it appropriate to select “not performed” for fields or categories in the risk stratification data section?**

Policy 6.1 requires data to be submitted every time the transplant program submits a justification form unless a test needed to obtain the data hasn't been performed since the last time the form was submitted. This information is collected in the risk stratification data (RSD) section of the justification forms. Per the policy, “Not Performed” is an option for fields in the risk stratification data section. Selecting “not performed” in this section will not disqualify the candidate for the status selected. The data being collected from these fields will aid in the possible future development of a heart allocation score.

If the RSD category requires “most recent” data to be reported, and no new tests have been performed since the last form submission and no new results are available, the transplant program should select “not performed.” The old values should not be re-submitted with new values.

However, if the RSD category requires “current” data to be reported, then even if the values for the fields are the same as the previous time the transplant program submitted a form, the program should re-enter the values, and should not select “not performed.”

**Devices**

**1. What devices qualify for statuses that require MSCD support?**

In policy, the use of the term mechanical circulatory support device (MSCD) is applicable to the following devices:

- VA ECMO
- Intra-aortic balloon pump (IABP)
- Total artificial heart (TAH)
- Percutaneous Devices
- Ventricular assist devices (VADs, including LVAD, RVAD, BiVAD)

The online toolkit includes a list of dischargeable devices and non-dischargeable devices.

[https://optn.transplant.hrsa.gov/media/2457/heart\\_device\\_brand\\_background.pdf](https://optn.transplant.hrsa.gov/media/2457/heart_device_brand_background.pdf)

**2. What if I don't know the device type?**

If your candidate is supported by a device that doesn't fall into one of the types of MSCD support listed above, you can apply for an exception.

**3. What is a non-dischargeable endovascular device?**

For the purposes of policy, “non-dischargeable” means that the device has not been approved by the FDA for use outside the hospital. Impella 2.5 and Impella 5.0 are both examples of percutaneous endovascular MSCDs. Any percutaneous endovascular circulatory support device qualifies a patient for status 2; while some of these devices might technically be dischargeable, patients must be admitted to the listing center to qualify for Status 2. Non-dischargeable surgically implanted ventricular assisted devices (i.e. those requiring a sternotomy or thoracotomy incision) are at higher risk of mortality and qualify for either status 1 (BiVAD) or status 2 (LVAD).

**4. Under status 3 criteria; regarding complication while on MCSD support - are the definitions/criteria the same as listed under the UNOS 1A(b) guidance?**

The definitions of device complications and failures in the new policy are not the exact same, but are very similar to the Criterion (b) guidance document.

**5. For status 3 patients with MCSD complication do they need to remain hospitalized?**

It depends on the type of complication the candidate is experiencing. If the candidate is experiencing mucosal bleeding associated with the MCSD, he or she must be admitted to the transplant hospital. If the candidate is supported by an MCSD and is experiencing hemolysis, pump thrombosis, right heart failure, infection, or aortic insufficiency, he or she does not have to be admitted to the hospital in order to qualify for status 3. However, there are other criteria for each of those complications that must be met in order to qualify.

**6. What status will a VAD that has shut off qualify for?**

If the candidate is admitted to the transplant hospital, this candidate would most likely qualify for status 2, under *Policy 6.1.B.iii: Mechanical Circulatory Support Device (MCSD) with Malfunction*. If the candidate needs another device due to the malfunction, the candidate may also qualify for other statuses. Always check the specific policy requirements for each status to ensure the candidate meets all status criteria.

**7. A candidate supported by a malfunctioning MCSD qualifies for status 2. If a pump exchange is performed, would the candidate still qualify for Status 2?**

No. The policy states that the malfunction must be one that places the patient at risk of imminent failure, so if you performed a pump exchange and it fixed it, then the candidate would no longer qualify for status 2 because the MCSD would no longer be at risk for that.

**8. Regarding percutaneous devices, a TandemHeart or an Impella 5.0 device, provides more support than an intra-aortic balloon pump (IABP) and Impella 2.5. Why are they given the same listing status?**

In determining criteria for listing status, the Thoracic Committee relied primarily on predictors of waitlist mortality. There was insufficient data to stratify patients based on the amount of flow required to resolve symptoms of cardiogenic shock, and flow requirements may vary depending on patient size and disease process. Finally, there is not data to suggest that the risks associated with the devices themselves are sufficiently different to justify different listing statuses. For all of these reasons, the critical qualifying criteria are that the patient had cardiogenic shock that required treatment with a temporary mechanical circulatory support device; the choice of device should be left to clinical practitioners and policy should not seek to influence that choice.

**9. How do you classify a patient on temporary extracorporeal Centrimag LVAD? And what if the LVAD circuit contains an oxygenator?**

Assuming the candidate meets all the clinical requirements in the criterion, the CentriMag itself would either qualify the candidate for status 2 under the non-dischargeable surgically implanted LVAD criterion or the percutaneous LVAD criterion, depending on insertion technique.

**10. Is the 30 day discretionary period for status 3 for candidates supported by LVADs required to be used immediately post-implant or is there a grace period?**

If a transplant program is electing to use the 30 days of discretionary time to register an LVAD candidate in status 3, the time can be used at any point after implant. The time is not required to be used all at once.

**11. Can a program list a candidate at Status 3 for 30 days even though the candidate was previously listed at Status 1A for 30 days prior to implementation?**

Even if a candidate already used 30 days of discretionary time in the current system for the candidate's current VAD, the candidate would still be eligible for an additional 30 days of discretionary time new 30 day cycle, even if that candidate is supported by the same VAD in the new system.

**12. Some statuses only require a user to enter the date on which a device was implanted. Which statuses require device date AND time for device initiation?**

Time of implant is required for the following:

- Policy 6.1.A.i: Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)
- Policy 6.1.B.iv: Percutaneous Endovascular Mechanical Circulatory Support Device
- Policy 6.1.B.v: Intra-Aortic Balloon Pump

**Hemodynamic Monitoring**

**1. What is the requirement for hemodynamic monitoring? Does it imply a pulmonary-artery (PA) catheter?**

Like previous policy, a PA catheter would qualify. The policy does not require a PA catheter specifically, but rather that there is daily monitoring of cardiac output and filling pressures. Currently, that primarily means a PA catheter, but there is a recognition that there are technologies emerging that might enable continuous monitoring of those two parameters: cardiac output and filling pressures without an invasive line and that would qualify as hemodynamic monitoring.

**Evaluating Success**

**1. What is the timeframe to evaluate if the new allocation system has an effect on short and long-term outcomes?**

We will evaluate the system every 6 months after it becomes effective, though it will take time to collect ample data to evaluate post-transplant outcomes. Most immediately, we will see the waitlist outcomes. We will evaluate every 6 months for the first 2 years, then probably yearly after that.

The metrics that the Committee will monitor are detailed in the briefing paper provided to the Board of Directors. [https://optn.transplant.hrsa.gov/media/2006/thoracic\\_brief\\_201612.pdf](https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf)

**2. The allocation changes will likely result in more urgent candidates being transplanted. Do you think this will effect long-term transplant outcomes?**

It is difficult to know for certain; the number of patients at this higher criteria who are expected to be transplanted is a relatively smaller number of patients, and there is some suggestion that by transplanting patients who are acutely ill or who are at more urgent statuses earlier they may be in better conditions when they get their transplants. It is hard to answer the hypothetical question when the allocation system is based on waitlist mortality. The post-implementation monitoring will be critical to answering that question and identifying whether it is a problem, and if it is a problem, responding by potentially changing the policy.

**3. Will there be a review of the use of ECMO as the new policy is instituted? Has there been any concern that the policy will drive the use of higher risk support systems? Is use of intra-aortic balloon pumps (IABPs) likely to increase?**

Concerns that policy would increase the use of ECMO was a theme that the committee heard throughout the development of this policy proposal, but the committee ultimately decided that it was appropriate to list candidates with VA ECMO in the highest status; that is partly why VA ECMO

candidates are only allowed to be status 1 for 7 days as opposed to 14 days. It is also important to remember that a candidate on VA ECMO must also meet the other clinical criteria that are listed in the policy. The committee will monitor how frequently candidates are registered for that status to see if there are experiencing any unintended consequences.

Similarly, the Committee will monitor the frequency with which candidates are registered for status 2 under the IABP criterion.

### **Multi-Organ and Multi-Listing**

#### **1. Is dual organ sharing addressed in this new allocation system?**

The policy for heart-lung allocation has been modified in the new allocation system. However, policies for other organ combinations have not changed.

#### **2. Does status 5 take into consideration the severity of a candidate's illness? If they qualify for a higher status for heart but need another organ, what status would they fall under?**

If a candidate qualifies for a status 5 because they are registered for another organ, but their heart condition is at such a level that they qualify for a higher heart status, then you should register your candidate in that higher status. You should always register your candidates in the highest status for which they qualify; some candidates might qualify for multiple statuses, but make sure that you are always registering them for the highest applicable status.

#### **3. How does this affect multi-center listing?**

The new policy does not affect a candidate's ability to be registered at more than one center. If the candidate is registered at more than one center, then both centers must update the candidate's registration at their center. Importantly, many of the criteria for statuses 1, 2, and 3 require a candidate to be admitted to the hospital at which they are registered, so a candidate cannot qualify for the same status at multiple hospitals if hospital admission is a requirement for that status.

### **Pediatrics**

#### **1. Will this allocation system also apply to pediatric candidates?**

No. These changes only apply to adult candidates (candidates registered at 18 years of age or older).

#### **2. Does a candidate registered less than 18 years of age maintain pediatric status for life or do they transition to the adult allocation?**

This is a policy that has not changed between the current and future system; if a candidate is registered when they are less than 18 years old and then turns 18 while still waiting for a heart, they are still treated as a pediatric candidate for the purposes of allocation. The only time that would change is if a candidate were removed from the waiting list altogether because of transplant or for some other reason and then subsequently re-registered after turning 18. In that case, the candidate would be an adult candidate upon re-registering.

### **Review Boards**

#### **1. Will extension requests be sent to a national or regional review board?**

Exception and extension requests will be sent to regional review boards. The only change is that the review board that reviews your exception or extension request will be from a different region.

**2. Is there a change in the composition of the review boards?**

We did not change the structure of review boards; however, regions will now evaluate cases outside of their regions.

**3. Will criteria be provided to define what it means to be unable to transition a candidate to a durable device?**

There are no criteria for demonstrating that a candidate is not able to be supported by a durable device. This is a clinical decision that the transplant program must make, and provide the rationale for that decision to the review board when requesting an extension for applicable statuses.

**Specific Patient Profiles**

**1. How will highly sensitized patients be prioritized?**

There is no change to the way sensitized candidates are prioritized in the new policy (all transplant programs and the OPO in the DSA must agree to allocate a heart to a sensitized heart candidate out of sequence). There is limited data on the impact of sensitization on outcomes due to the fact that centers are not required to submit PRA or unacceptable antigen data. We'll collect sensitization data as part of this policy change to help inform future changes to sensitization policy.

**2. What is the correct status for a candidate who has already received a heart transplant and now requires another one?**

Status 4 contains a criterion for candidates in need of re-transplant. This is the lowest status a re-transplant candidate can be, but you should register the candidate in the highest status for which he or she qualifies.

**3. Will inotropes be necessary prior to insertion of an intra-aortic balloon pump (IABP)? If not, don't you anticipate more IABP placement?**

To qualify for status 2 under *Policy 6.1.B.v: Intra-Aortic Balloon Pump (IABP)*, inotropes are not a requirement before placement. However, a candidate can only qualify for this status if the IABP was placed for treatment of cardiogenic shock. The status is valid for up to 14 days and a weaning attempt must be performed in order to extend. Any changes in allocation may have unintended consequences on clinical decision making and if the outcomes among patients with IABP change (due to a changed patient profile listed on IABP), the Committee expects to make changes to the policy to reflect the changed outcomes.

**4. What status does a candidate supported by continuous mechanical ventilation qualify for?**

Continuous mechanical ventilation was removed as a criterion so you will have to evaluate that patient and figure out how they qualify using the criteria in the new system.

**5. Will a candidate supported by a total artificial heart (TAH) that has been discharged from the hospital still be able to qualify for status 2?**

Yes. To qualify for status 2, candidates with total artificial hearts do not need to be admitted to the hospital.

**6. Does the new allocation system address blood group O patients?**

The changes to the allocation are not specific to any specific blood type.

**7. What status will patients who are experiencing arrhythmia issues and cannot have monitoring devices in place, or inotropic support, qualify for?**

If patients do not meet the specific criteria in policy, the transplant program would have to request an exception and document why the waitlist mortality would be expected to be similar to candidates meeting the specified criteria.

**8. How do you classify an LVAD patient with persistent GI bleed, intolerant of anticoagulation and therefore increasing risk of thrombosis?**

There are specific criteria for patients on VADs who have specific bleeding associated with their VAD that would enable them to get a higher status on the assist device alone; for patients who are not on a ventricular assist device or don't meet the specific criteria, the exception pathway is always open to patients.

**9. Is it realistic to expect that Status 6 patients will never be transplanted unless they get sicker and move up in status? If so, why have a status 6?**

Candidates in status 6 in the new system are most similar to candidates that are status 2 in the current system. Status 2 candidates currently are at lower priority than all of the patients above them, but they do still get offers and there are significant numbers of transplants that occur at that status. Changing the number from 2 to 6 doesn't mean that there are more candidates waiting above them; there will still be offers made to candidates listed at status 6.

**10. What if I need to inactivate my candidate?**

Like the previous system, candidates on the waitlist that are not currently suitable for transplant should be registered in status 7, which is the inactive status.

**11. In the criteria for status 4 (Policy 6.1.D.ii: Inotropes without Hemodynamic Monitoring), one requirement is that the candidate's cardiac index (CI) must be less than 2.2 L/min/m<sup>2</sup> within 7 days of submission of the justification form. What do we do with those patients that have been on an inotrope for a longer period and the CI is higher than 2.2 on the inotrope? Do we have to perform hemodynamic testing, including a right heart catheter, in order for the candidate to qualify under this criteria?**

The candidate will need to meet the criteria specified in policy in order to qualify for that status. There may be some unintended consequences during the transition for patients on inotropes without hemodynamic monitoring (Policy 6.1.D.ii Inotropes without Hemodynamic Monitoring) because of the timing of the required hemodynamic data.

The following options are available during the transition for candidates currently supported by inotropes without hemodynamic monitoring:

1. The candidate can be registered in any other status for which they qualify
2. Administer new hemodynamic testing if it is clinically appropriate
3. If the transplant program determines it is not clinically appropriate to reassess the candidate's hemodynamics, but the transplant program believes the candidate has an expected waitlist mortality and potential for benefit similar to other patients in Status 4, the transplant program can request an exception.
  - a. Pertinent data to include in an exception request, that the review boards might consider in granting the request, include data demonstrating that other than the timing of the catheterization, the candidate would qualify Status 4 based on hemodynamics obtained at the time of initiation of inotropes.

## **Transition between Current Allocation System and New Allocation System**

### **1. If a patient is Status 1A now how is that time carried over in the new system?**

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. For example, if a candidate is listed in status 1 in the new system, the system will calculate that candidate's waiting time as all time at new status 1 plus all time previously accumulated at status 1A. For example, the waiting time for a candidate in status 3 will be all time accumulated at new status 3, plus all time accumulated at new status 2, plus any time accumulated at new status 1, plus any time accumulated at old status 1A.

### **2. Will currently registered candidates be allowed to finish out their current status (and exception) if they are actively listed when the changes apply?**

No. When the new system goes live, it will immediately begin allocating hearts based off of the new statuses.

### **3. Is the transition period to the new system going to be an auditable item on any future regulatory surveys?**

Changes to OPTN compliance monitoring will only occur when the new system is fully live, not during the 30 day transition period. However, justification form that is submitted during the transition period and determines the candidate's active status when the new system is fully implemented after the transition period may be subject to review as part of a routine site survey. The OPTN does not have purview over any other regulatory surveys that may occur.

### **4. What will happen to candidates that are registered as temporarily inactive (status 7) during the transition phase?**

If the candidate is inactive, they will stay inactive in the new system unless you activate them. If you realize they should be active at some point during the transition period, you'll need to register them in the appropriate status in the current system as well as the appropriate status in the new system.

## **Additional Resources**

Please visit the [Adult Heart Allocation Toolkit](#) for additional resources. The toolkit includes useful resources, including policy language, infographics, and patient education materials.

A patient brochure is currently available in digital form: <https://transplantliving.org/organ-facts/heart/heart-faq/>.