OPTN

Briefing to the OPTN Board of Directors on

Guidance and Policy Clarifications Addressing Adult Heart Allocation Policy

OPTN Heart Transplantation Committee

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Contents

Guidance and Policy Clarifications Addressing Adult Heart Allocation Policy

Affected Policies:	*Policy 6.1.A.ii: Non-dischargeable, surgically implanted, non-endovascular biventricular support device* *Policy 6.1.C.vi: Mechanical Support Device with Infection* *Policy 6.1.D.ii: Inotropes without Hemodynamic Monitoring*
Affected Guidance:	*Guidance for Adult Heart Exceptions for Status 2 Candidates Experiencing Cardiogenic Shock*
Sponsoring Committee:	*Heart Transplantation*
Public Comment Period:	*August 4, 2020 – October 1, 2020*
Board of Directors Date:	*December 7, 2020*

Executive Summary

The Organ Procurement and Transplantation Network (OPTN) implemented modifications to the adult heart allocation system on October 18, 2018.[1] Among the changes, more clinical statuses were added to better capture transplant candidates' medical acuity. It was believed that more closely aligning patients' with their medical acuity would lead to transplant programs submitting fewer exception requests. However, when members of the OPTN Thoracic Organ Transplantation Committee (the OPTN Heart Transplantation Committee was not operationalized until July 1, 2020) reviewed the first 12 months of monitoring data, they noted that the number of exception requests had not decreased. In fact, the volume of Status 2 exception requests raised concerns that certain temporary therapies implemented in the 2018 modifications were being used for longer periods of time than the policy intended.

This proposal provides a guidance document to educate the Heart transplant community about the use of adult heart Status 2 exception requests. The Heart Transplantation Committee (hereafter, the Committee) also identified opportunities to clarify parts of policy. As a result, the proposal contains policy and guidance changes designed to improve and clarify components of existing adult heart allocation policy.

- Policy: Amend policy language involving when certain hemodynamic data should be reported, and the initial qualifying and extension timeframes associated with certain statuses and medical conditions. One of the policy changes will require the submission of new data elements.
- Guidance: Clarify the types and amount of information that should be provided to the heart Regional Review Board (RRB) members to assist them with objectively evaluating an exception request for a candidate being supported by the temporary therapies of a Percutaneous Endovascular Mechanical Circulatory Support Device or an Intra-Aortic Balloon Pump (IABP). The guidance focuses on improving the usefulness of the information in the clinical narratives of such patients. The guidance document does not create or change OPTN policy.

[1] OPTN, Policy Notice, Additional Clarifications to the Adult Heart Allocation System Policy Language. Accessed April 13, 2020. https://optn.transplant.hrsa.gov/media/2538/thoracic_policynotice_201807_heart.pdf

Background

In December 2016, the OPTN Board approved changes to heart allocation policy.[2] The changes increased the number of adult heart statuses from three to six in order to better stratify the most medically urgent patients based on their conditions. The changes were implemented in October 2018, and represented the first major amendments to the adult heart allocation system in about a decade.

In response to an increasing number of candidates listed at Status 1A, the OPTN Board approved the creation of three additional heart statuses "to better stratify the most medically urgent heart transplant candidates."[3] The change was in response to an increasing number of candidates listed at Status 1A, but who had varying degrees of medical urgency as defined by waiting list mortality. [4] From July 31, 2006 to November 30, 2015, the number of candidates listed at the highest status, Status 1A, had grown from 58 to 376.[5] Because some candidate groups did not fall neatly into any of the statuses, transplant programs were forced to rely on exception requests to address their needs.

The more granular statuses were intended to ensure that the sickest candidates have access to donor hearts first. The additional classifications and criteria were also expected to reduce the need for transplant programs to submit exception applications, which had also grown substantially since the 2006 changes. The policy changes also recognized the increased use Mechanical Circulatory Support Devices (MCSD) by transplant programs.

Issues Identified With OPTN Adult Heart Allocation Policy

In 2019, the Committee identified two policies from 2018 for additional amendments. The first involves *Policy 6.1.D.ii: Inotropes without Hemodynamic Monitoring*. The 2018 modifications require that a candidate's cardiac index be less than 2.2. L/min/m^2 within seven days of submission of the justification form[6]. Some transplant programs questioned why the date the cardiac index was measured was being associated with form submission instead of the start of inotropic therapy.[7] A transplant program submitted the following:

> *"We did not feel it was in the patient's best interest to stop the inotropes, precipitate decompensation and risk worsening renal function or worse, cardiogenic shock and possible inability to recover."*

[2] OPTN, *Briefing Paper, Proposal to Modify the Adult Heart Allocation System*. Accessed October 11, 2020. https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf
[3] OPTN, Briefing Paper, Proposal to Modify the Adult Heart Allocation System, December 2016, p. 1.
[4] OPTN, *Briefing Paper, Proposal to Modify the Adult Heart Allocation System*, p. 2. Accessed October 11, 2020. https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf
[5] OPTN, *Briefing Paper, Proposal to Modify the Adult Heart Allocation System*, p. 2. Accessed October 11, 2020. https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf
[6] OPTN, *Policy 6.1.D.ii: Inotropes without Hemodynamic Monitoring*. Accessed October 11, 2020. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf
[7] OPTN, *Modifications to the Adult Heart Allocation System: Frequently Asked Questions*, question 11, p. 7. Accessed June 28, 2020. https://optn.transplant.hrsa.gov/media/2688/adult-heart_revised-faq_20181008.pdf

Transplant program staff point out that inotrope administration is likely to stabilize a candidate's condition.[8] However, for the candidate to meet the cardiogenic shock requirements within seven days of form submission, the transplant program may need to remove the candidate from the inotropes.

Furthermore, the monitoring might require an invasive, right-heart catheterization procedure that could put the candidate at further risk. Possible risks include bruising where the catheter is inserted and potential for puncturing the vein during insertion and resulting excessive bleeding. Other, rarer complications can occur, including a pulmonary artery rupture, or even air leaking into the heart or chest area, that could lead to death. [9] In addition, for candidates who have been receiving inotropic therapy, the program may have to stop the therapy in order for the candidate to experience cardiogenic shock again.

A transplant program may choose not to perform a right-heart catheterization, or to attempt to wean a candidate from a medication in order to capture the cardiac index value if the candidate is in a stable condition. In such circumstances, a transplant program may consider requesting an exception or listing the candidate at another status. However, as previously discussed, relying on an exception request is not optimal for a candidate. First, it is up to the discretion of the transplant program if they want to submit an exception request. Second, exception requests must be approved by a RRB, increasing the potential that a candidate will not be assigned to the requested status. Likewise, listing a candidate at a lower status is not optimal because the lower status may not adequately reflect a candidate's medical urgency From October 18, 2018 through October 17, 2019, 240 candidates were added to the waitlist at Status 4 under the Inotropes without Hemodynamic Monitoring criteria.[10]

The Committee also considered increasing the initial qualifying and extension timeframes associated with assigning a patient to Status 4 as a result of *Policy 6.1.D.ii*. Such candidates can remain at the status for up to 90 days from submission of the Heart Status 4 Justification Form. After the initial 90 days, the status can be extended by the transplant program every 90 days by submission of another Heart Status 4 Justification Form.

Based on the potential invasiveness associated with measuring cardiac index, the Committee considered how frequently the value is needed. In the post-implementation period evaluated in the one-year monitoring report, median days to transplant for Status 4 candidates was 262 days. [11] Under the pre-2018 allocation system, candidates considered similar to those in Status 4 now were allowed to remain at a similar status for an almost indefinite amount of time. For comparisons of pre- and post-implementation medical urgency statuses, Status 1B in the pre-implementation phase can be approximated with Statuses 4 and 5 in the post-implementation period.[12] Under the previous policy

[8] OPTN, *Briefing Paper, Proposal to Modify the Adult Heart Allocation System*, p. 11. Accessed October 11, 2020. https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf

[9] Johns Hopkins Medicine, *Right Heart Catheterization*, June 2020, Available at https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/right-heart-catheterization

[10] OPTN, *One-Year Monitoring of the Heart Allocation Proposal*, Table 2, p. 13. Accessed October 11, 2020. https://optn.transplant.hrsa.gov/media/3701/data_report_thoracic_committee_heart_subcommittee_20200227_rpt1_revised_508_compliant.pdf

[11] OPTN, "One-Year Monitoring Report on Revisions to the Adult Heart Allocation System," Presentation to Thoracic Organ Transplantation Committee, February 27, 2020, slide 14.

[12] OPTN, *One-Year Monitoring of the Heart Allocation Proposal*, p. 5. Accessed October 11, 2020. https://optn.transplant.hrsa.gov/media/3701/data_report_thoracic_committee_heart_subcommittee_20200227_rpt1_revised_508_compliant.pdf.

framework, a candidate who qualified for Status 1B was permitted to retain the status "for an unlimited period."[13] Moreover, a transplant program could extend a candidate's time at Status 1B without providing any new documentation. Several Committee members cited their own program's protocols establishing 180 days as the timeframe between right heart catheterizations.

If implemented, the proposed changes will require transplant programs to begin reporting new data elements on the Adult Heart Status 4 Justification Form. Data that programs may already collect, but have not reported. Currently, a transplant program must provide the dosage amount associated with the inotrope or inotropes administered to the patient. A program must also provide the values for the cardiac index and pulmonary capillary wedge pressure and the test dates of when the values were recorded. The test date provided for the cardiac index is validated to ensure it occurred within seven days prior to the date the justification form was submitted. If the provided test date is outside of the acceptable range, the transplant program will not be able to continue completing the justification form.

Under the proposed changes, a transplant program must still report the dosage associated with the inotrope or inotropes administered to the patient. However, a program will also need to provide the date indicating when the inotrope was first administered. The date will be validated against the test date provided by the program for the cardiac index to ensure the dates are within seven days of each other. The four additional data fields, a date field associated with each of the four listed inotropic treatments, are the only new data collection associated with the proposal. Similar date fields exist on the Adult Heart Status 3 Justification Form for candidates to qualify for *Policy 6.1.C.v: MCSD with Right Heart Failure*.

Also considered were the initial qualifying periods and extension periods associated with Policy *6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Devices.* A candidate assigned to this status and type of therapy initially qualifies for up to 14 days. A transplant program can extend a candidate using this criteria for up to an additional 14 days. The criteria for this therapy were created as part of the 2018 modifications. The Committee agreed to limit who could qualify for Status 1 when supported by a device that was not approved by the Federal Drug Administration (FDA) for use outside of a hospital to those with biventricular support devices.[14] The policy changes also created a status criterion in Status 2 for those candidates supported by Left Ventricular Assist Devices (LVAD) that are not approved by the FDA for use outside of the hospital. Both status criterion established 14 days as both the initial qualifying period and the extension period.

The Committee agreed that the Status 1 criterion would be more appropriate as seven days to make it more consistent with other Status 1 criteria. Furthermore, establishing the qualifying and extension periods as seven days better aligns it with the timeframes established in *Policy 6.1.A.i: Veno-Arterial Extra Corporeal Membrane Oxygenation (VA ECMO)*.

[13] OPTN, *Briefing Paper, Proposal to Modify the Adult Heart Allocation System*, p. 43. Accessed October 11, 2020. https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf.
[14] OPTN, *Briefing Paper, Proposal to Modify the Adult Heart Allocation System*, p. 12. Accessed October 11, 2020. https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf.

2018 Policy Changes Have Not Reduced Exception Request Volume

In addition to creating new statuses, the policy changes implemented in 2018 created additional qualifying criteria for the most urgent statuses.[15] Additional qualifying criteria were established for Status 1 under the VA ECMO criteria, Status 2 under the Percutaneous Endovascular MCSD and the IABP, and Status 3 under the multiple inotropes with hemodynamic monitoring criteria. Policy required that the therapies be used to treat cardiogenic shock.

The proposed policy changes were expected to better account for relative waiting list mortality rates of all candidate groups, and treat all patients more equitable. [16] This included those candidates whose conditions were not well accounted for under the previous allocation system, and for whom their transplant programs had to submit exception requests However, data on the number of exception requests leading up to and following the policies changes suggest that there was no reduction in the use of exception requests.

During development of the 2018 policy changes, the Committee members agreed that a major problem of the allocation system was the use of too many exception requests.[17] For example, it was reported that between January 2014 and December 2015, transplant programs submitted a total of 5,878 Status 1A and Status 1B exceptions requests (5,340 Status 1A exception requests and 538 Status 1B exception requests). This works out to 245 exception requests per month based on 22 months.

Status 1A in the previous system is roughly equivalent to Statuses 1, 2, and 3 in the new allocation system. Statuses 4 and 5 in the new allocation system are roughly equivalent to Status 1B in the previous system. Information provided in the One-Year Monitoring Report of the new adult heart allocation system found that during the 13 months spanning September 2018 through October 2019, a total of 3,711 exception requests were submitted for candidates listed at adult Statuses 1, 2, 3, or 4. (Exception requests are not available for Status 5 under current policy). This works out to about 265 exception requests per month.

The current Committee was concerned by the lack of reduction in exception requests. On top of those concerns, the Committee members were also aware that during development of the previous policy, the initial and extension timeframes associated with certain temporary therapies were criticized for being too long and incentivizing transplant programs to leave their candidates on the temporary support longer than necessary.[18] In light of these concerns, they decided to focus on addressing the use of Status 2 exception requests. The members agreed that clarifying what information should be provided as part of an exception request could be beneficial without having to revise policy.

This is particularly true regarding Status 2 exception requests. For example, in the year following implementation, the percentage of adult heart waiting list additions qualifying by an exception at time

[15] OPTN, *Briefing Paper, Proposal to Modify the Adult Heart Allocation System*, p. 10. Accessed October 11, 2020. https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf.
[16] OPTN, *Modifications to the Adult Heart Allocation System*, question 11, p. 7. Accessed October 11, 2020. https://optn.transplant.hrsa.gov/media/2688/adult-heart_revised-faq_20181008.pdf
[17] OPTN, Briefing Paper, *Proposal to Modify the Adult Heart Allocation System*, p.2. Accessed October 11, 2020. https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf.
[18] OPTN, Briefing Paper, *Proposal to Modify the Adult Heart Allocation System*, p. 11. Accessed October 11, 2020. https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf.

of listing was greatest for adult Status 2 (**Table 1**).[19] Of the 722 candidates listed at Status 2, 227 (31%) qualified by exception rather than the criteria established in policy.[20]

Table 1: Adult Heart Waiting List Additions With an Exception for Statuses 1 – 4 at Listing Post-implementation (October 18, 2018 – October 17, 2019)

Adult Status	Number of Waiting List Additions With an Exception	Total Number of Waitlist Additions	Percentage of Waitlist Additions by Exception
1	32	168	19.05%
2	227	722	31.44%
3	86	483	17.81%
4	249	1,581	15.75%

Source: OPTN, *One Year Monitoring of the Heart Allocation Proposal,* Table 2, p. 12.

Concerned by what was perceived as a still large volume of exception requests for listing at Status 2, as opposed to qualifying by the criteria established in policy, the Committee looked more closely at the clinical narratives provided for the reasons for exceptions. During August 2019, Committee leadership reviewed the redacted clinical narratives of more than 200 adult heart Status 2 exception requests submitted from June 1 through July 31, 2019. They included both initial exception requests and extension exception requests.

While the review only examined 30 days' of exception requests and was mainly exploratory, some trends were identified, suggesting transplant programs could benefit from a guidance document. The review found some requests were lacking certain hemodynamic data that the reviewers believed was baseline information that should have been included, while others contained no hemodynamic data. Other requests included clinical narratives providing hemodynamics that were not appropriate based on policy for the status being requested, such as systolic blood pressure greater than 90 mmHg or pulmonary capillary wedge pressure less than 15 mmHg. Furthermore, some clinical narratives reviewed met the criteria associated with hypertrophic/restrictive cardiomyopathy or adult congenital heart disease, for which guidance exists. However, the transplant program did not reference the guidance and potentially missed an opportunity for the candidate to qualify for the status being requested.[21]

The reviewers expressed concern that the information being provided in the exceptions they reviewed was not adequate for a hypothetical review board member to make a decision. While exceptions exist to address those instances where a candidate does not meet the criteria established in policy, the transplant program is supposed to use objective evidence to demonstrate that a candidate has at least the same medical urgency as other candidates in that status, and the same potential for benefit. The reviewers believed that programs were not providing enough information or the correct types of information to demonstrate their candidate had the same medical urgency.

In evaluating exception requests, the RRB members are tasked with determining whether a "candidate has an urgency and potential for benefit comparable to that of other candidates at the requested

[19] OPTN, One Year Monitoring of the Heart Allocation Proposal, Table 2, p. 12.
[20] OPTN, One Year Monitoring of the Heart Allocation Proposal, Table 2, p. 12.
[21] OPTN, Review Board Guidance for Hypertrophic/Restrictive (HCM/RCM) Cardiomyopathy Exception Requests, and OPTN, Review Board (RB) Guidance for Adult Congenital Heart Disease (CHD) Exception Requests.

status."[22] When submitting an exception request, a transplant program is supposed to demonstrate the similar urgency and potential benefit using acceptable medical criteria.[23] However, the policy does not define what constitutes acceptable criteria.

Nonetheless, RRBs approved more than 90 percent of the Status 2 exception requests submitted in the year following implementation of the new allocation policy.[24] The lack of guidance pertaining to what information should be included in the narrative likely results in wide variability of the detail and appropriateness of requests. This makes it difficult for RRB members to make consistent decisions.

Committee members indicated that the findings in the one-year monitoring report reinforced their efforts to address Status 2 exceptions for candidates supported by Percutaneous Endovascular MCSD and IABP through a guidance document. The guidance helps: standardize exception requests for Status 2 candidates supported by the temporary therapies; clarify criteria indicative of VAD contraindications; ensure that patients are only placed on Percutaneous Endovascular MCSD or IABP when those therapies are most appropriate; and provide structure needed by RRB members to evaluate.[25]

Purpose

The Committee has carefully monitored the impacts resulting from the allocation policy changes implemented in 2018. Based on those changes, the Committee identified opportunities to better operationalize existing policy through clarifications and amendments, including changes that could better align policies based on the intended medical urgencies.

In addition to the policy clarifications, the Committee concluded that addressing the use of exceptions associated with Status 2 candidates being treated with IABP or Percutaneous Endovascular MCSD would likely have a substantial impact towards aligning the behavior of the transplant programs and regional review boards more closely with the adult heart policy. The proposed guidance document is designed to provide transplant program staff who prepare exception requests and regional review board members who review the requests with more effective practices regarding the types of information and level of detail that should be included in any request. The Committee's intent is to establish a standard or baseline of information that would be reasonably expected to describe a candidate's clinical status. Such a standard, consistently applied, should minimize the differences currently found across the requests and improve the ability of the regional review boards to consistently apply policy across the requests.

The purpose of this proposal is to change policy to reduce the potential for unnecessary invasive procedures for certain adult heart Status 4 patients, better align the initial qualifying and extension timeframes of Status 1 therapies, and reorder the list of device infections associated with MCSDs. The proposal also creates guidance for transplant programs and Regional Review Boards to use when preparing and submitting Status 2 exception requests.

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[22] OPTN, *Policy 6.4: Adult and Pediatric Status Exceptions.* Accessed October 11, 2020. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf.
[23] OPTN, Adult heart status 2 exception criteria justification form. Accessed in UNet℠ October 29, 2019.
[24] OPTN, One-Year Monitoring of the Heart Allocation Proposal, Table 16, p. 66.
[25] OPTN, Thoracic Organ Transplantation Committee, meeting summary, February 27, 2020. Accessed on October 11, 2020. https://optn.transplant.hrsa.gov/media/3695/20200227_thoracic_heartsubcommittee_meeting-summary.pdf

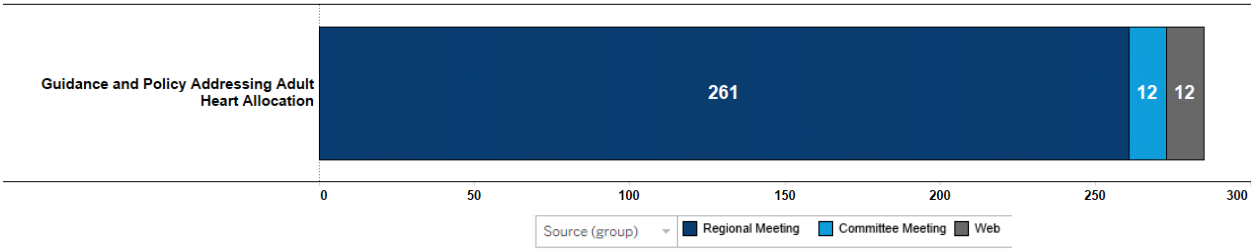
The Committee submits the following proposal for the Board consideration under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[26]

Because transplant programs are required to report additional data, the Committee also submits the following proposal for the Board consideration under the authority of the OPTN Final Rule, which states, "An organ procurement organization or transplant hospital shall…submit to the OPTN…information regarding transplant candidates, transplant recipients, [and] donors of organs…."[27] The OPTN shall "maintain records of all transplant candidates, all organ donors and all transplant recipients"[28] and shall "…receive…such records and information electronically…"[29]

Public Comment Sentiment

The proposal was available for public comment from August 4 through October 1, 2020. **Figure 1** shows that a combination of 285 sentiment responses and comments submitted to the OPTN website were received during that time. A total of 261 sentiment responses about the proposal were received through the 11 regional meetings. The members of the Transplant Coordinators Committee (TCC) discussed the proposal and submitted 12 sentiment responses. The remaining 12 entries were submitted by individuals, and on behalf of transplant programs and professional organizations. (The sentiment responses and submitted comments can be found on the OPTN website.)

Figure 1: Volume of Comments by Source



Source: OPTN, Public Comment. Accessed October 11, 2020. https://optn.transplant.hrsa.gov/governance/public-comment/guidance-and-policy-addressing-adult-heart-allocation/

The proposal received strong support in all eleven regional meetings, and from the TCC members. Of the 285 sentiment responses submitted, 209, or 73 percent supported the proposal. Within those, about 18 percent strongly supported the proposal. "Neutral/Abstain" responses accounted for 22 percent.

Figure 2 categorizes the sentiment information submitted as part of the 11 regional meetings.[30] In total, 192 responses supported the proposal, 63 responses were neutral or abstained, and the remaining six responses were opposed. The proposal received an overall regional score of 3.9 out of a total of 5.0.

[26] 42 CFR §121.4(a)(1).
[27] 42 CFR §121.11(b)(2).
[28] 42 CFR §121.11(a)(1)(ii).
[29] 42 CFR §121.11(a)(1)(iii).
[30] This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only includes attendees at that regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

Figure 2: Sentiment Support for the Proposal, by Region

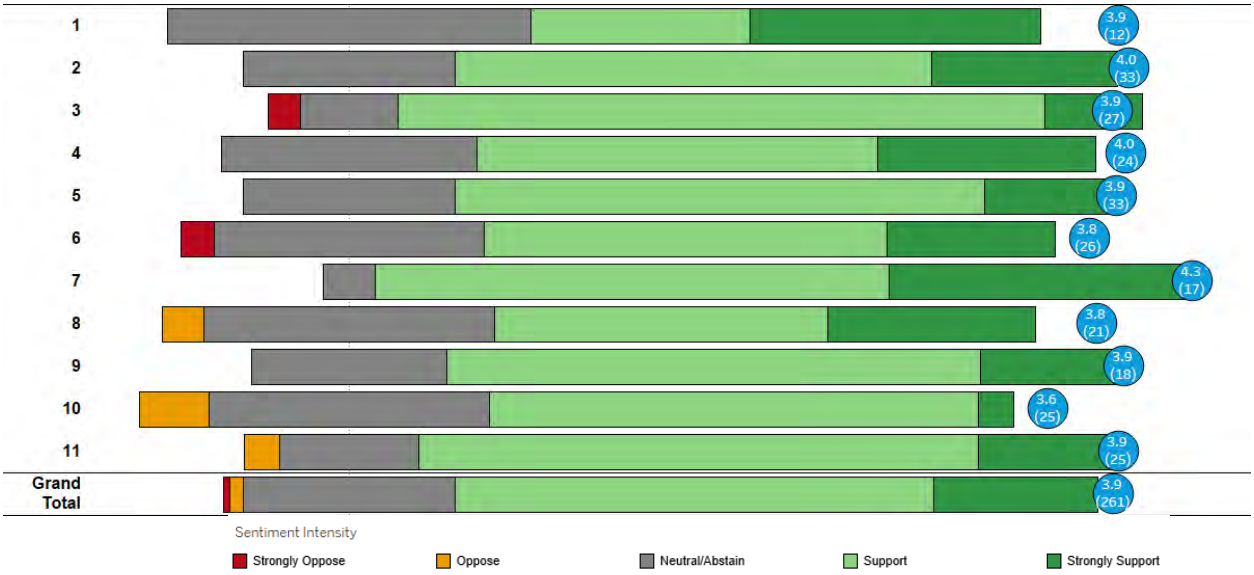
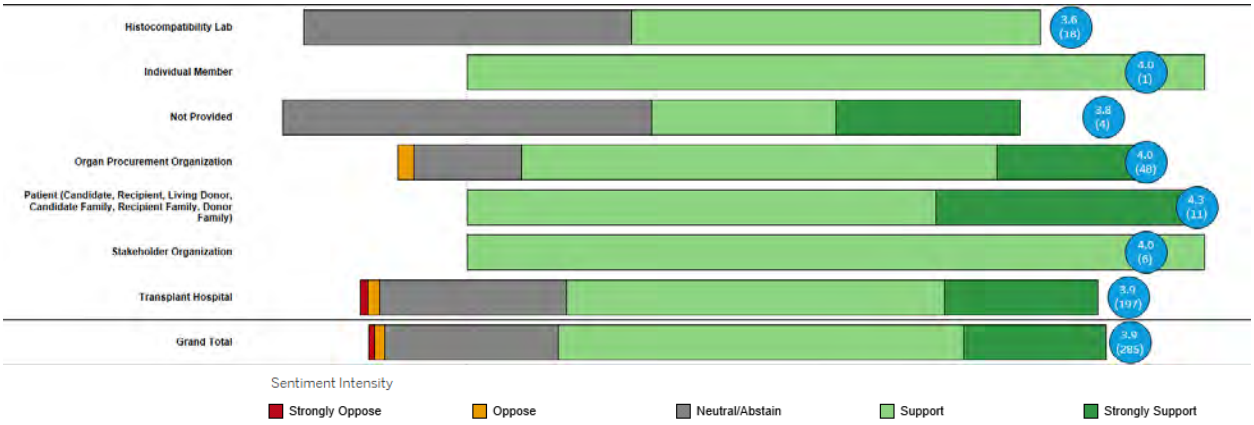


Figure 3 identifies support for and opposition to the proposal by OPTN member type. A total of 285 responses and comments were cast by member type.[31] The overall sentiment score was the same as by region, 3.9 out of a total of 5.0. Transplant hospitals accounted for 69 percent of the sentiment responses submitted. Within the responses provided by transplant hospitals, support was 74 percent. All 12 of the patient-related responses supported or strongly supported the proposal.

Figure 3: Sentiment Support for the Proposal, by Member Type



Four professional organizations submitted written comments regarding the proposal. All four organizations supported the overall proposal. They also included specific comments addressing the individual sections of the proposal. Some of the specific comments are summarized later in this section of the document. For example, all four indicated that the proposed guidance will promote standardization of the information included with exception requests. American Society of Transplantation (AST) written response suggested that current policy addressing the use of Inotropes

[31] This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only includes attendees at that regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

without Hemodynamic Monitoring is "clinically questionable" and the proposed change is appropriate. The Organization for Donation and Transplant Professionals (NATCO) also pointed out the problem with the current policy, stating that patients should not have to be weaned to capture the cardiac index value.

The proposed policy changes and guidance material received the support of the transplantation community during the public comment period. Changing when transplant programs should measure the cardiac index of a Status 4 candidate being treated with inotropes without hemodynamic monitoring from submission of the heart justification form to the date of inotrope administration received a great deal of community support. Furthermore, the guidance document created to clarify the information programs should submit with Status 2 exceptions requests for candidates being treated for temporary cardiogenic shock was also well supported during public comment. The proposed policy changes to the initial qualifying and extension timeframes for certain Status 1 and Status 4 therapies also received public support; however, members also raised questions about the appropriateness of the changes based on the candidates' medical conditions.

Proposal for Board Consideration

This proposal makes several amendments to adult heart allocation policy. The changes include modifying *Policy 6.1.D.ii: Inotropes without Hemodynamic Monitoring* to require that a candidate's cardiac index be collected within seven days of the initiation of inotropes. Other policy changes the proposal requires include reducing the initial qualifying and extension timeframes from 14 to seven days for candidates being treated with a non-dischargeable, surgically implanted, non-endovascular biventricular support device, and a re-ordering of the listed MCSD device infections.

The proposal also contains guidance for Status 2-related exception requests to assist Regional Review Board members with their assessments and decision-making. The guidance also serves as a resource for transplant programs staff who are responsible for completing the clinical narrative portion of an exception request with the appropriate amount and type of information on behalf of their candidates.

Support for Changing When Cardiac Index Should Be Collected for Status 4 Candidates, With Some Comments on Extending Initial Qualifying and Extension Timeframes

Policy 6.1.D.ii: Inotropes without Hemodynamic Monitoring requires that a candidate have a cardiac index of less than 2.2 L/min/m^2 within 7 days prior to submission of the Heart Status 4 Justification Form [emphasis added].[32] The heart transplant community has questioned whether it is appropriate to associate the timing of measuring the cardiac index to submission of the form. The Committee members, who also had concerns about the policy, agreed that a policy change was needed. According to members of the Committee, they had heard from multiple transplant programs that potential transplant recipients were being weaned from their inotropic treatments just so the program could capture a cardiac index value, as required by Policy 6.1.D.ii.

This proposal removes the policy language associated with submission of the Adult Heart Status 4 Justification Form as the baseline for measuring when a candidate's cardiac index met the requirement

[32] OPTN, Policy 6.1.D.ii: Inotropes without Hemodynamic Monitoring.

(**Exhibit 1**). In its place, the following language is proposed "Cardiac index of less than 2.2 L/min/m^2 within 7 days prior *to inotropic administration or while on inotrope infusion as specified* [emphasis added]" by subsequent criteria in the policy. The Committee's intent in proposing the change is to ensure that patients are not put at risk to obtain the cardiac index value. Permitting programs to submit cardiac indexes associated with when the candidate started inotropes clarifies the Committee's intention that a candidate should not be weaned from inotropes or that a right heart catheterization is required to demonstrate that the candidate had a cardiac index indicating cardiogenic shock.[33]

Exhibit 1: Existing Criterion and Proposed Change to *Policy 6.1D.ii: Inotropes without Hemodynamic Monitoring* Associated with Cardiac Index Measurement

Existing Criterion	Proposed Criterion
1. Cardiac index of less than 2.2 L/min/m^2 within 7 days prior to ~~submission of the *Heart Status 4 Status Justification Form*~~	1. Cardiac index of less than 2.2 L/min/m^2 within 7 days prior to inotropic administration or while on inotrope infusion as specified below

The Committee also acted to increase the initial qualifying and extension timeframes for these Status 4 candidates from "up to 90 days" to "up to 180 days." The Committee based its decision on what is believed to be standard practice for many programs. Extending the timeframe results in less invasive testing of a stable candidate who may be waiting for a transplant for some time.

The policy changes will result in the collection of additional data. The data will indicate the date associated with the inotrope administration. The dates will be used to validate that the cardiac index value was measured within seven days of inotrope initiation, as opposed to within seven days prior to form submission as currently established in policy. The Data Advisory Committee (DAC) reviewed the data fields in their role as an operating committee with responsibility for all data collection activity. The DAC members did not have any concerns about the proposed data fields.

The Committee reviewed and discussed the results of public comment and concluded that sentiment supports sending the proposal to the Board with no changes.[34] Most of the comments submitted about the proposed change supported it. NATCO supported the proposal because it would eliminate the need to wean a patient from inotropes in order to measure cardiac index.[35] A transplant hospital commended the Committee "on recognizing this flaw in the current policy" and proposing a correction.[36] An anonymous commenter stated that most other statuses require hemodynamics prior to initiation of therapy, so associating this requirement with submission of the form makes it very confusing.[37]

[33] Meeting Summary for April 17, 2020 meeting, OPTN, Thoracic Organ Transplantation Committee, https://optn.transplant.hrsa.gov/media/3783/20200417_thoracic_meeting-summary.pdf (accessed June 6, 2020).
[34] OPTN, Public Comment webpage, Guidance and Policy Clarifications Addressing Adult Heart Allocation Policy, accessed on October 5, 2020. https://optn.transplant.hrsa.gov/governance/public-comment/guidance-and-policy-addressing-adult-heart-allocation/.
[35] OPTN, Public Comment webpage, Guidance and Policy Clarifications Addressing Adult Heart Allocation Policy, NATCO comments submitted on September 30, 2020, accessed on October 5, 2020. https://optn.transplant.hrsa.gov/governance/public-comment/guidance-and-policy-addressing-adult-heart-allocation/
[36] OPTN, Public Comment webpage, Guidance and Policy Clarifications Addressing Adult Heart Allocation Policy, Tampa General Hospital comments submitted on September 30, 2020, accessed on October 5, 2020. https://optn.transplant.hrsa.gov/governance/public-comment/guidance-and-policy-addressing-adult-heart-allocation/
[37] OPTN, Public Comment webpage, Guidance and Policy Clarifications Addressing Adult Heart Allocation Policy, "Anonymous"

Support for the Committee's proposal to extend the qualifying and extension timeframes was more mixed. Some at the regional meetings expressed concern that extending the timeframes to "up to 180 days" could lead transplant programs to reduce the medical management of these patients. As a result, a patient's medical conditions could deteriorate without their program realizing until the 180-day mark is reached. For example, a commenter pointed out that the impacts of pulmonary hypertension can be quiet and subtle, and might be missed if transplant programs have up to 180 days to perform monitoring. Other commenters asked that if the proposal is implemented, that the Committee monitor the outcomes of patients assigned to this status to determine if there are any associated medical management issues.

Several other commenters, including the professional organizations reported their agreement with the extensions. For example, the AST and NATCO responses both indicated that the extensions are appropriate for these patients. AST's response noted that the extending the timeframes is reasonable "given the median wait time and lack of restrictions on prior 1B status" patients before the new allocation system was implemented in 2018.[38] Other commenters acknowledged that some transplant programs have already set their standard at 180 day intervals for measuring hemodynamics for patients being treated by this therapy.

Mixed Support for Decreasing Initial Qualifying and Extension Timeframes for *Policy 6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device*

A candidate listed at Status 1 under *Policy 6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device* is eligible to stay at the status for up to 14 days under the initial application. The candidate's stay can be extended every 14 days by submission of another extension form. Candidates are not required to meet any additional criteria in order to extend under this criteria. This proposal will limit the initial qualifying period and the extension period to up to seven days for a candidate assigned to Status 1 by a non-dischargeable, surgically implanted, non-endovascular biventricular support device. Limiting the initial and extension timeframes more closely aligns this criterion with the timeframes established in *Policy 6.1.A.i: Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)*.

The Committee sought to make the initial qualifying timeframes and extension timeframes consistent within the Status 1 criteria. Median days to transplant for Status 1 candidates was four days during the post-implementation period of October 18, 2018 through October 17, 2019.[39] During that time, 22 candidates were added to the waiting list under Policy 6.1.A.ii, while 102 candidates were added under the VA ECMO criteria.[40]

comment submitted on September 30, 2020, accessed on October 5, 2020. https://optn.transplant.hrsa.gov/governance/public-comment/guidance-and-policy-addressing-adult-heart-allocation/.

[38] OPTN, *Briefing Paper, Proposal to Modify the Adult Heart Allocation System*, p. 43. Accessed October 11, 2020. https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf.

[39] OPTN, One-Year Monitoring of the Heart Allocation Proposal to Modify the Heart Allocation System, February 20, 2020, Table 9, p. 48.

[40] OPTN, One-Year Monitoring of the Heart Allocation Proposal to Modify the Heart Allocation System, Table 2, p. 12.

Multiple commenters stated that the current initial qualifying and extension timeframes of up to 14 days for Status 1 candidates is appropriate and should not be changed. They pointed out that Status 1 patients on biventricular support are the "sickest of the sick" on the waiting list. Some also stated that there is little chance that the conditions of such candidates will improve within seven days. Permitting patients on biventricular support to remain in Status 1 for 14 days appropriately extends their chances of receiving an acceptable offer. Other comments against the proposed reduction, suggested that reducing the number of days from 14 to 7 would likely increase a transplant center's workload. The Transplant Coordinators Committee submitted the following comment, "the change to 7 days for Status 1 patients may increase [a program's] administrative burden since those patients will need extensions or new justification forms [submitted more] frequently."

Other comments indicated that the high medical urgency of these Status 1 candidates is a reason to support the proposed change. For example, NATCO found the reduced timeframe reasonable given the high medical urgency of this group of patients. A transplant program agreed with the proposed change and noted that "the patient population is clinically very dynamic and fluid and re-evaluation of the appropriateness of [the candidates'] Status 1 listing on a weekly basis is reasonable." The Transplant Coordinators Committee, which had noted an increased administrative burden from the proposal, acknowledged in its written response "that Status 1 patients are the most medically urgent and need to be re-evaluated frequently."

The Committee considered the feedback received from the regional meetings and public comment, as well as the discussion with the Transplant Coordinators Committee. The Committee agreed to send the proposal to the Board with no changes.

Reordering Listing of Evidence of Device Infections

In order to better clarify the policy, the Committee is proposing to rearrange the order of the table identifying the evidence of device infection associated with *Policy 6.1.C.vi: Mechanical Circulatory Support Device (MCSD) with Infection*. It was recommended that the criterion of positive culture of material from the pump pocket of an implanted device should follow the criterion referring to debridement of the driveline. This change groups the two bacteremia-specific infections together. The proposed change only involves re-ordering the listed device infections. The Committee agreed to send the proposal to the Board with no changes.

Strong Support for Guidance Document

A goal of the 2018 Modifications to the Adult Heart Allocation System policy changes was to reduce the number of exceptions by better accommodating the clinical scenarios addressed in policy. However, as stated in the Background section, monitoring reports following implementation found that the anticipated reduction in exception request volume had not occurred. Moreover, the majority of the exception requests submitted under the new policy are being approved by the regional review boards. Reasons why the number of exception requests have not decreased may include:

- The community is still familiarizing itself with the new policy
- The community has found a pathway to circumvent the standard criteria
- The community has found some of the criteria more stringent
- The new policy still does not adequately accommodate most clinical scenarios

- The regional review board members are unsure of how to interpret the new policy and so are reluctant to deny exception requests
- The community is using temporary support devices in ways that were not considered when the new policy was developed

The Committee drafted the guidance document with the goal of assisting heart transplant programs to complete exception requests more uniformly for Status 2 candidates who are supported by Percutaneous Endovascular MCSD and IABP. The guidance is also intended to help the RRBs evaluate exception requests by identifying certain standard information that should be included with each request. The following scenario is intended to demonstrate what the Committee members identified as an appropriate level of detail in a clinical narrative as part of an initial exception request. The example is meant for illustrative purposes only, and does not reflect an actual patient.

> *Our patient is a 62 year-old male with ischemic cardiomyopathy, ejection fraction (EF) 10%, who was placed on an IABP on May 15 for refractory cardiogenic shock demonstrated by cardiac index (CI) 1.8, pulmonary capillary wedge pressure (PCWP) 18, and systolic blood pressure (SBP) 95 and intermittent angina on milrinone 0.5 mcg/kg/min. After implantation his PCW dropped to 12, SBP rose to 110 and CI rose to 2.2 and has had no further angina. He was listed Status 2 on May 16. His current hemodynamics are right atrium (RA) 5-8, pulmonary artery (PA) 40s/20s, PCWP 12-15, and CI 2.1-2.4. We are requesting this exception to the SBP under 90 because attempts to increase inotropes worsened angina and more aggressive diuresis or GATA4, Mef2c, and Tbx5 (GMT) resulted in worsened renal function.*

The following is what an appropriate and descriptive clinical narrative might appear like if the fictional candidate's program was to submit an extension request:

> *In the last 48 hours, we did not attempt to wean from the IABP as the patient remains in persistent cardiogenic shock as evidenced by worsening CI to 1.8 on full IABP support as well as decline in mixed venous oxygen saturation SVO2 to take 48%. At this time, we are worried that patient is not a candidate for durable LVAD due to inability to take warfarin due to the current gastrointestinal (GI) bleeds.*

The Committee expects the guidance will assist transplant programs to demonstrate that a candidate has both the medical urgency and potential for benefit comparable to that of other candidates at this status.[41] The guidance document describes the expected level of detail.

Several public comments cited the importance of programs submitting consistent and standardized information for Status 2 exception requests. One transplant program stated that the current lack of consistency "has the potential to advantage and disadvantage patients at different programs." Another program described the current use of exceptions as creating "disparities in the transplant process." The program went further by providing general examples of requests their staff had reviewed including a request citing a potential risk as the reason a patient should be listed at Status 2, and because the patient and the program refused a LVAD, even though the individual was eligible.

Like the transplant programs, all four professional organizations commenting on the proposal expressed concern that programs may be playing by different rules under the current process. They also agreed

[41] OPTN, Adult heart status 2 exception criteria justification form. Accessed in UNet℠ October 29, 2019.

with the Heart Committee's effort to standardize the information being provided. AOPO's response stated that by identifying certain standard information for reporting, the Committee is "ensuring that candidates with similar medical urgency are treated equally." While AST's written response supported the guidance overall, the organization did serve the Committee with a warning that "there is still much room for 'gaming' in the criteria for contraindications to LVADs," continuing on to mention that more concrete definitions may be needed.

NOTA and Final Rule Analysis

The Committee developed the policy proposal under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[42]

The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with §121.8," which requires that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;…(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section."

This proposal:

- **Is based on sound medical judgment**[43] because the policy modifications were made after analyzing OPTN data to better align candidates' medical urgencies with policy and clarify that programs are not required to stop inotropic treatment to obtain a cardiac index value.
- **Seeks to achieve the best use of donated organs**[44] **by** ensuring organs are allocated and transplanted according to medical urgency. Because the underlying goal of the changes to adult heart allocation policy was to ensure that the most medically urgent candidates are prioritized, these policy changes further that goal by refining the requirements for candidates to qualify for the higher urgency statuses.
- **Is designed to…promote patient access to transplantation**[45] **by** giving similarly situated candidates equitable opportunities to receive an organ offer. This proposal refines status criteria to ensure that candidates that are medically similar to each other have an equitable opportunity for transplant based on their urgency status.

The changes recommended by the Committee also preserve the ability of a transplant program to decline an offer or not use the organ for a potential recipient,[46] and it is specific to an organ type, in this case heart.[47]

[42] 42 CFR §121.4(a)(1).
[43] 42 CFR §121.8(a)(1).
[44] 42 CFR §121.8(a)(2).
[45] Ibid.
[46] 42 CFR §121.8(a)(3).
[47] 42 CFR §121.8(a)(4).

The proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, and the Committee does not expect impacts on the following aspects of the Final Rule:

- Shall be designed to avoid wasting organs. The changes are not anticipated to impact the number of organs recovered but not transplanted.
- Shall be designed to avoid futile transplants. The changes are not anticipated to result in transplantation of recipients that are unlikely to have positive post-transplant outcomes.
- Shall be designed to promote the efficient management of organ placement. The changes are not anticipated to affect the costs and logistics of procuring and transplanting organs.
- Shall not be based on the candidate's place of residence or place of listing, except to the extent required [by the aforementioned criteria]. The changes are not based on the candidate's place of residence or place of listing.

In addition, because it will require the submission of official OPTN data that are not presently collected by the OPTN, the Committee submits the following proposal for Board consideration under the authority of the OPTN Final Rule, which states, "An organ procurement organization or transplant hospital shall…submit to the OPTN…information regarding transplant candidates, transplant recipients, [and] donors of organs…."[48] The OPTN shall "maintain records of all transplant candidates, all organ donors and all transplant recipients."[49] This proposal will allow the OPTN to collect more complete data on heart transplant candidates and maintain such data in the OPTN dataset.

The OPTN issues the guidance for the operation of the OPTN.[50] This guidance will support the operation of the regional review boards by assisting the reviewers with evaluating exception requests. The OPTN Final Rule requires the Board to establish performance goals for allocation policies, including "reducing inter-transplant program variance."[51] This guidance document will assist in reducing inter-transplant program variance in the performance indicators initially adopted by the Board when it modified the adult heart allocation system. These performance indicators include exception requests stratified by medical urgency status.[52]

Consideration of Potentially Disadvantaged Groups and Transition Procedures

The Final Rule also requires the OPTN to "consider whether to adopt transition procedures" whenever organ allocation policies are revised to ensure that those waiting for transplant are treated "no less favorably than they would have been treated under previous policies".[53] The Committee identified the population of patients assigned to Status 1 under *Policy 6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device* as potentially being treated "less favorably than they would have been under the previous policies" if the proposed changes are approved by the Board of Directors. The members considered the potential impact on that population of reducing the

[48] 42 CFR §121.11(b)(2).
[49] 42 CFR §121.11(a)(1)(ii).
[50] 2019 OPTN Contract Task 3.2.4: Development, revision, maintenance, of OPTN Bylaws, policies, standards and guidelines for the operation of the OPTN.
[51] 42 CFR §121.8(b)(4).
[52] OPTN Briefing Paper: Proposal to Modify the Adult Heart Allocation System. December 2016. https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf (accessed on June 24, 2020).
[53] 42 CFR § 121.8(d).

initial qualifying and extension timeframes from 14 days to seven days. The Committee agreed that the shorter timeframe was appropriate based on the medical urgency associated with Status 1 candidates, as well as the information that the median wait to transplantation was four days for Status 1 candidates. The Committee also took into consideration that this is a very small population of candidates. Additionally, because of the small population, any extension forms open at the time the policy change was implemented could be held open to accommodate the 14-day window they were started under, and then converted to seven days following expiration or any other changes. Therefore, the Committee does not recommend adopting a transition plan for these patients.

Alignment with OPTN Strategic Plan[54]

Improve waitlisted patient, living donor, and transplant recipient outcomes:
The proposal intends to improve waitlisted patient outcomes by ensuring that adult donor hearts are provided to the sickest candidates first. The proposed guidance document clarifies the information transplant programs should provide as part of an adult Status 2 exception request. To make it easier for programs, the guidance includes a template that can be copied and pasted into the clinical narrative section of an exception request programs can use to make it easier The clarifications will help ensure adult donor hearts are provided to the sickest candidates first, and that therapies for temporary cardiogenic shock are used for temporary support only. Additionally, the proposal seeks to ensure that patients receiving the Status 4 therapy of Inotropes without Hemodynamic Monitoring are not subjected to unnecessary invasive procedures for transplant programs to measure cardiac index (CI). Associating CI collection with the start of inotropic treatment should reduce patient risk.

Implementation Considerations

Member and OPTN Operations

Operations affecting Transplant Hospitals

Transplants programs will need to educate their personnel on the details associated with the policy modifications and the availability of the guidance document. Transplant programs may need to update their training protocols related to the completion of adult heart status justification forms related to initial, extension, and exception applications. Program staff should provide more substantive information detailing the reasons a candidate meets the clinical criteria associated with the adult status criteria than has previously been provided. The update may require closer interaction with the physicians and other clinical care providers. Programs with adult Status 1 patients who meet the criteria for non-dischargeable, surgically implanted, non-endovascular biventricular support device will need to more frequently update their adult heart status 1 justification forms in order to extend their candidates at the status.

Transplant programs assisting adult heart Status 4 candidates who are meeting the criteria for inotropes without hemodynamic monitoring will need to provide the date the candidate's inotrope administration started in order to validate that the cardiac index value was collected within seven days of the start of inotrope administration. A transplant program will provide the date when inotrope administration was started on the Adult Heart Status 4 Justification Form.

[54] For more information on the goals of the OPTN Strategic Plan, visit https://optn.transplant.hrsa.gov/governance/strategic-plan/.

Operations affecting Histocompatibility Laboratories

This proposal is not expected to affect the operations of Histocompatibility Laboratories.

Operations affecting Organ Procurement Organizations

This proposal is not expected to affect the operations of Organ Procurement Organizations.

Operations affecting the OPTN

Programming changes are required as part of the proposal. First, four new data fields will be collected indicating the date of inotrope initiation. Currently, a transplant program must indicate that a patient requires treatment with at least one of the following intravenous inotropes by providing the dosage being administered: Dobutamine, Dopamine, Epinephrine, and Milrinone. Under the proposed policy change, a transplant program will also be required to report the date associated with the initiation of the inotropes. The date information will be used to validate that the cardiac index was measured within seven days of inotrope administration.

Currently, similar dates are already captured on the justification forms associated with *Policy 6.1.C.v: Mechanical Circulatory Support Device with Right Heart Failure*. Transplant programs are already required to enter the dosage associated with the therapy being used. Under the policy change, programs would also have to enter the date the inotrope therapy was initiated. Transplant program staff can enter the date in a MM/DD/YYYY format. In an effort to promote data consistency, transplant programs also have the ability to use a calendar link programmed into the forms to select the date. This approach should limit formatting issues associated with the dates.

In addition, changes are needed to the heart justification forms and to the timing associated with the extension forms. The changes will also necessitate special circumstances for managing the justification forms that were in place prior to the implementation of these policy changes. This is estimated as a large IT effort based largely on handling the 'in-flight' forms and required database modifications.

This proposal may require the submission of official OPTN data that are not presently collected by the OPTN. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in §121.11 of the OPTN Final Rule will be collected through OMB approved data collection forms. Therefore, after OPTN Board approval, the forms will be submitted for OMB approval under the Paperwork Reduction Act of 1995.[55] This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

Projected Fiscal Impact

This proposal will require the submission of official OPTN data that are not presently collected by the OPTN. As part of the proposed changes to *Policy 6.1.D.ii: Inotropes without Hemodynamic Monitoring* transplant programs must provide the date of inotrope initiation for up to four inotropes. The dates will be used as a factor in determining whether the candidate is eligible for listing at Status 4 under this

[55] Organ Procurement and Transplantation Network Contract HHSH250201900001C, Performance Work Statement at Task 3.5: Collect official OPTN data to support the operations of the OPTN.

criterion. Currently, the OPTN does collect the initiation dates for this criterion, although it collects this information as part of *Policy 6.1.C.v: Mechanical Circulatory Support Device with Right Heart Failure*.

Minimal or no expected fiscal impact for OPOs, transplant hospitals, or histocompatibility labs.

Projected Impact on the OPTN

IT estimates a medium to large-size implementation effort of 648 hours. The implementation will involve with modifications to the adult heart Status 4 justification forms, adding new logic for validating when the cardiac index measures was obtained, amending the days at status for two justification forms, and managing the transition plan for justification forms that are submitted following Board approval but prior to implementation. Research estimates 60 hours total to assist IT during implementation. PCR included an estimate of 40 hours related to implementation for time spent assisting IT staff.

PCR, Research, and IT each reported ongoing annual monitoring activities. IT estimates 65 hours annually for regression testing of adult forms and Research estimating 40 hours per year for performing the analyses described in the monitoring report. PCR estimated ongoing activities requiring about 50 hours annually related to responding to member questions about the policy changes and the guidance materials.

Post-implementation Monitoring

Member Compliance

The Final Rule requires that allocation policies "include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program."[56]

The proposed language will not change the current routine monitoring of OPTN members. Site surveyors will continue to review a sample of medical records, and any material incorporated into the medical record by reference, to verify that the data reported in UNet℠ to justify a candidate's status are consistent with documentation in the candidate's medical record.

Policy Evaluation

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate."[57] On October 18, 2018, the OPTN implemented substantial changes to the adult heart allocation system. The new policy clarifications will be monitored in conjunction with and on the same timeline as the October, 2018 system changes. Specific additions to the monitoring plan will include changes in the number of initial and extension requests for

- Status 1 Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device (Policy 6.1.A.ii),and
- Status 4 Inotropes without Hemodynamic Monitoring (Policy 6.1.D.ii).

[56] 42 CFR §121.8(a)(7).
[57] 42 CFR §121.8(a)(6).

As sample size permits, the waiting list mortality rate for these criteria for Status 1 and Status 4 candidates may be reported and compared based on pre- and post- policy clarification date.

To monitor the guidance document, the number of transplants by adult heart status and exception status will be compared based on pre- and post- implementation of the guidance. As sample size permits, the waiting list mortality rate for Status 2 candidates will be compared pre- and post-implementation of the guidance. The OPTN and the Scientific Registry of Transplant Recipients (SRTR) contractors will work with the Committee to define any additional analyses requested for monitoring.

Conclusion

The Heart Transplantation Committee proposed addressing issues identified when the adult heart allocation system changes were implemented in October 2018. The changes proposed for *Policy 6.1.D.ii: Inotropes without Hemodynamic Monitoring* intend to reduce the chance that the condition of a stable patient is not put in jeopardy to obtain a cardiac index measurement, and that the initial and extension qualifying periods are appropriate. The initial and qualifying periods for *Policy 6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device* can be shortened to reflect the high medical urgency of such candidates and the median length of time they remain in the status before being transplanted. Finally, aspects of OPTN policy are clarified by reordering the symptoms identified in MCSD and device infections.

Adult heart transplant programs should consider this guidance when submitting exception requests on behalf of Status 2 candidates supported by a Percutaneous Endovascular MCSD or by an IABP. RRB members are encouraged to consult this resource when assessing exception requests on behalf of Status 2 candidates supported by a under Percutaneous Endovascular MCSD or by an IABP.

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

6.1 Adult Status Assignments and Update Requirements

6.1.A Adult Heart Status 1 Requirements

6.1.A.ii Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device

A candidate's transplant program may assign a candidate to adult status 1 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by a surgically implanted, non-endovascular biventricular support device and must remain hospitalized because the device is not FDA-approved for out of hospital use.

This status is valid for up to ~~14~~7 days from submission of *the Heart Status 1 Justification Form*. This status can be extended by the transplant program every ~~14~~7 days by submission of another *Heart Status 1 Justification Form.*

6.1.C Adult Heart Status 3 Requirements

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

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by an MCSD and is experiencing a pump-related local or systemic infection, with *at least one* of the 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 for up to:
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 driveline exit site and the device	14 days from submission of *the Heart Status 3 Justification Form*.
Debridement of the driveline with positive cultures from sites between the driveline exit site and the device	14 days from submission of *the Heart Status 3 Justification Form*.
Positive culture of material from the pump pocket of an implanted device	90 days from submission of *the Heart Status 3 Justification Form*.
Bacteremia treated with antibiotics	42 days from submission of *the Heart Status 3 Justification Form*.
Recurrent bacteremia that recurs from the same organism within four weeks of completing antibiotic treatment to which the bacteria is susceptible	90 days from submission of *the Heart Status 3 Justification Form*.
~~Positive culture of material from the pump pocket of an implanted device~~	~~90 days from submission of *the Heart Status 3 Justification Form*.~~

After the initial qualifying time period, this status can be extended by the transplant program by submission of another *Heart Status 3 Justification Form*.

6.1.D Adult Heart Status 4 Requirements

6.1.D.ii Inotropes without Hemodynamic Monitoring

A candidate's transplant program may assign a candidate to adult status 4 if the candidate is supported by a continuous infusion of a positive inotropic agent, and meets *all* of the following:

1. Cardiac index of less than 2.2 L/min/m^2 within 7 days prior to ~~submission of the *Heart Status 4 Status Justification Form*~~ inotropic administration or while on inotrope infusion as specified below
2. Pulmonary Capillary Wedge Pressure greater than 15 mmHg
3. 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 for up to ~~90~~180 days from submission of *the Heart Status 4 Justification Form*. After the initial ~~90~~180 days, this status can be extended by the transplant program every ~~90~~180 days by submission of another *Heart Status 4 Justification Form*.

#

Guidance for Adult Heart Exceptions for Status 2 Candidates Experiencing Cardiogenic Shock

Recommendations

The following resource provides guidance for transplant program staff responsible for completing the clinical narrative portion of an initial exception request or an extension exception request on behalf of a candidate to be assigned at status 2. Transplant programs are expected to demonstrate that a candidate has both the medical urgency and potential for benefit comparable to that of other candidates at this status.[58] In addition, the guidance is intended to provide RRB members with a roadmap to certain, useful information necessary for making informed decisions.

The guidance is organized in three sections: a clinical description of the patient, factors impacting the program's attempt to wean the candidate, and applicable contraindications to a VAD. TThese have been identified as important components for any description of why the temporary therapies of Percutaneous Endovascular MCSD or IABP was used to treat a candidate's cardiogenic shock. The list of clinical criteria in this section should serve as evidence that the candidate remains with persistent hemodynamic instability. When completing the clinical narrative of an exception request, transplant program staff should be submitting clinical measurements and not just indicating the presence or absence of a condition.

It is understood that the guidance will not address all cases. The guidance is intended to promote consistent review of these diagnoses and summarize the Committee's recommendations to the OPTN Board of Directors. This resource is not OPTN Policy, so it does not carry the monitoring or enforcement implications of policy. It is not an official guideline for clinical practice, nor is it intended to be clinically prescriptive or to define a standard of care. This resource is intended to provide guidance to transplant programs and the Regional Review Boards.

TEMPLATE

Section 1: Characterization of the Patient

Candidate (Waiting list ID#) is a (age) year old (male/female) with (Dilated/Ischemic/Restrictive) Cardiomyopathy who is status post (S/P) Percutaneous Endovascular MCSD or IABP on (implant date) in this transplant program's Intensive Care Unit on Inotropes (provide agents and dose) and Pressors (provide agents and dose). Patient has been listed as a Status (1/2/3/4/5/6) since

Current hemodynamics are as follows (If a Swan-Ganz catheter is available,):

Right Atrium (RA):	
Pulmonary Artery (PA):	
Pulmonary Capillary Wedge Pressure (PCWP):	
Cardiac Index (CI):	

[58] OPTN, Adult heart status 2 exception criteria justification form. Accessed in UNet℠ October 29, 2019.

We are requesting this exception for _ (specify data item)_____
because _____

Section 2: Inability to Wean Candidate

In the last 48 hours, we did not attempt weaning from Percutaneous Endovascular MCSD or IABP as the candidate remains in persistent cardiogenic shock as evidenced by: (provide the values for one or more items)

Hypotension Mean Arterial Pressure (MAP):	
Reduced Cardiac Index (CI):	
Elevated PCW:	
Low $SvO_{2\ or}$ PA sat	
Worsening End Organ Function:	
Requiring increasing doses of inotropic agents or pressors:	
Ventricular Tachycardia (VT):	
Other:	

Section 3: Contraindications to LVAD

The following should be considered as general information that might be expected when describing why a patient is not a candidate for durable LVAD Support (extension only).

1. Severe Right Heart Failure (RHF)
    a. Echo: Severe TR; TASPE < 7.5mm; RVEF < 20%; RV/LV size > 0.75
    b. Hemodynamic: RA:PCW > 0.54; RVSWI < 250; PAPi < 1
2. Surgical Contraindications
    a. Mechanical Aortic Valves (AV)
    b. Mechanical Mitral Valves (MV)
    c. Small Left Ventricle (LV) Cavity
    d. Left Ventricular Thrombus
    e. VSD
    f. Body size BSA < 1.1
    g. Other: (Describe)
3. Need for Multi-organ Transplant
    a. Renal
    b. Liver
4. Blood Dyscrasias
    a. Thrombocytopenic
    b. Hypercoagulable
    c. Contraindication to Warfarin
5. Active Co-morbidity
    a. Infection
        i. Date: _(mm/dd/yyyy)
        ii. Site:_____
        iii. Culture:_____
    b. Recent CVA

i. Date: _(mm/dd/yyyy)

c. Bleeding

i. Date: _(mm/dd/yyyy)

ii. Site: _____

6. Re-current Refractory Ventricular Arrhythmias
7. Other: _____

Note: It is recommended that requesting programs not rely solely on patient preference when submitting an extension exception request to maintain a candidate at Status 2.

Conclusion

Adult heart transplant programs should consider this guidance when submitting exception requests on behalf of Status 2 candidates supported by a Percutaneous Endovascular MCSD or by an IABP. RRB members are encouraged to consult this resource when assessing exception requests on behalf of Status 2 candidates supported by a under Percutaneous Endovascular MCSD or by an IABP.
Adult heart transplant programs should consult this resource when submitting exception requests on behalf of Status 2 candidates supported by a Percutaneous Endovascular MCSD or by an IABP. The information is provided in the form of a template that transplant program staff should consider copying and pasting into the narrative section of the exception request. Review Board members should also consult this guidance when assessing exception requests of such candidates. However, the guidance is not prescriptive of clinical practice.

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