OPTN

Briefing to the OPTN Board of Directors on

Modify Heart Policy to Address Patient Safety Following Device Recall

OPTN Heart Transplantation Committee

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Modify Heart Policy to Address Patient Safety Following Device Recall

Affected Policies:	*6.4: Adult and Pediatric Status Exceptions*
Sponsoring Committee:	*Heart Transplantation*
Public Comment Period:	*August 3, 2022-September 28. 2022*
Board of Directors Meeting:	*December 5, 2022*

Executive Summary

Mechanical circulatory support devices (MCSD) have long been an essential treatment for severe heart failure.[1] MCSDs are commonly used for bridge-to-transplant therapy, as well as temporary bridge-to-recovery therapy and a permanent solution to severe heart failure. Despite the increased reliance on MCSDs as heart failure therapies, Organ Procurement and Transplantation Network (OPTN) policy does not specifically address how to ensure patient safety if, and when, an implanted heart device is subject to a recall by the United States Food and Drug Administration (FDA). Beginning in June 2021 and continuing through June 2022, the FDA issued multiple recall notices related to a specific type of MCSD. In a February 2022 letter to the OPTN Heart Transplantation Committee (Committee), the device manufacturer stated that the device's delay in restarting or failing to restart was linked to a total of ten deaths worldwide.

After receiving the letter and as the FDA recalls continued, the Committee unanimously supported an emergency policy action to address patient safety concerns in the U.S. associated with the MCSD. The OPTN Executive Committee, acting on behalf of the OPTN Board of Directors,[2] approved the Committee's policy change on July 11, 2022 as allowed for in the emergency actions pathway established in OPTN Bylaw 11.7. The emergency policy allows a transplant program to proactively assign a heart candidate with a FDA recalled heart device to a more urgent and appropriate heart status. Transplant programs can now request an exception for an adult heart status 1, 2, or 3 in the event that a transplant candidate's implanted MCSD is subject to a recall by the FDA, even if the candidate is not hospitalized at the time.

The policy change was implemented on July 14, 2022 and will expire on July 13, 2023 without further action. This emergency policy is being submitted to the OPTN Board of Directors for permanent consideration.

[1] Sen, Ayan, Joel S. Larson, Kianoush B. Kashani, Stacy L. Libricz, Bhavesh M. Patel, Pramod K. Guru, Cory M. Alwardt, Octavio Pajaro, and J. Christopher Farmer. "Mechanical Circulatory Assist Devices: a Primer for Critical Care and Emergency Physicians." Critical Care (London, England) 20, no. 1 (2016): 153–153. https://doi.org/10.1186/s13054-016-1328-z. Stehlik, Josef, and James K Kirklin. "The Long and Winding Road to an Effective Left Ventricular Assist Device: The Demise of Medtronic's HVAD." Circulation (New York, N.Y.) 144, no. 7 (2021): 509–11. https://doi.org/10.1161/CIRCULATIONAHA.121.056027.

[2] OPTN Bylaws, *Article IV Executive Committee*, (December 6, 2021), ("Considers any issues that require expedited action between meetings of the Board of Directors.").

Purpose

The OPTN Executive Committee's approval of this emergency policy in July 2022 addresses situations where an implanted MCSD has the potential for impending failure and the implanted device or one of its implanted components is under recall by the FDA. The approved emergency policy is submitted to the OPTN Board of directors for approval as permanent policy.

The life-threatening complications associated with the failure of an implanted heart device required emergency action to protect patient safety. The circumstances surrounding a recent device recall underscore the magnitude of the problem, which this policy addresses. On June 3, 2021, the FDA issued a letter to health care providers stating that issues had been identified with a durable left ventricular assist device (LVAD), and the sale and distribution of the device was being stopped. The issues included:

- Increased neurological adverse events and mortality associated with the internal pump implanted in the device recipient, and
- The potential for the internal pump to stop, resulting in delayed restarts or a failure to restart[3]

Subsequent FDA recalls have been issued for additional pieces of equipment associated with the durable VAD as a system. **Table 1** identifies the significant actions taken by the FDA related to the device since June 2021.

Table 1: Dates and Events of a Recent Heart Device Recall[4]

Date	Event
June 3, 2021	FDA issued a letter to healthcare providers stating that the sale and distribution of the system has been stopped because of: • An increased risk of neurological adverse events and mortality associated with the internal pump • A potential for the internal pump to stop. If the internal pump stops, it may delay restarting or fail to restart
August 12, 2021	FDA issued a recall notice indicating the FDA classified the June 3, 2021 actions to stop the sale and distribution of the system because the product could cause serious injury or death
April 28, 2022	FDA issues a letter to healthcare providers to alert them to the possibility that patients who have the device and system and appear to present with pump thrombosis may have a weld defect in the internal pump causing the pump to malfunction
June 10, 2022	FDA issued a recall notice indicating the FDA classified the April 2022 recall related to actions to alert healthcare providers to a possibility of a weld defect in the internal pump because the product could cause serious injury or death
June 23, 2022	FDA issued a recall notice indicating the FDA classified the May 2022 recall related to a welding defect affecting internal Battery components from a single lot because the product could cause serious injury or death

During the Heart Committee's presentation to the Executive Committee regarding the policy changes, the members discussed how electrical issues involving the device's batteries, controller, and cables

[3] United States Food and Drug Administration, "Stop New Implants of the Medtronic HVAD System – Letter to Health Care Providers," June 3, 2021, https://www.fda.gov/medical-devices/letters-health-care-providers/stop-new-implants-medtronic-hvad-system-letter-health-care-providers, (accessed July 12, 2022).
[4] United States Food and Drug Administration website, https://www.fda.gov/medical-devices/cardiovascular-devices/medtronic-heartware-ventricular-assist-device-hvad-system, (accessed July 8, 2022).

contributed to the restart issues. Exchanging the device's battery pack as well as the normal usage of the controller and cables were identified as factors that could increase the likelihood that the device had a delayed restart or failed to restart. Because most device recipients are not admitted to a hospital, they are responsible for maintenance of the batteries, controller, and cables. It was determined that the way the device's battery packs are maintained can result in damage to the overall system, including a reduction in battery life.

Furthermore, it has been noted that the probability of the implanted pump experiencing a delayed restart or failing to restart increases with the amount of time the person is supported by the implanted device.[5] It is the consensus of the OPTN Heart Transplantation Committee members that additional FDA recalls are likely to be issued in the future.[6]

Transplant candidates with the current recalled device are typically registered on the waiting list as adult heart status 4. They are considered clinically stable and therefore, not admitted to a hospital. As shown in **Table 2**, there were a total of 170 registrations on the heart waiting list as of June 17, 2022, where it was indicated the device in question was implanted. Of those 101 registrations, almost 60 percent, were assigned to status 4. The recalls are associated with specific lot or model numbers which are not collected by the OPTN and therefore the data presented indicate the number of candidates who may be potentially impacted by the recalls.

Table 2: Heart Waiting List Registrations Where Candidate Has a Potentially Recalled Device, June 17, 2022

Adult Heart Status	Number of Registrations With a Potentially Recalled Device	Registrations With Potentially Recalled Device as Percentage of Total
1	0	0.0%
2	5	2.9%
3	22	12.9%
4	101	59.4%
5	0	0.0%
6	1	1.0%
7 (Temporarily Inactive)	41	24.1%
Total	**170**	**100.0%**

Candidates who have the recalled device implanted faced two-policy related issues preventing them from prospectively being assigned to a higher medical urgency status. First, in order to meet the eligibility criteria for status 2 associated with *Policy 6.1.B.ii: Mechanical Circulatory Support Device (MCSD) with Malfunction*, a candidate must be experiencing the malfunction at the time the status assignment is requested. That is unlikely for most of those impacted. Second, *Policy 6.4: Adult and Pediatric Status Exceptions* requires that a candidate must be hospitalized in order to seek an exception for assignment at adult heart statuses 1, 2, and 3. Prior to approval and implementation of the policy changes creating a new exception pathway, the candidates impacted by the recall were ineligible for

[5] United States Food and Drug Administration website, https://www.medtronic.com/content/dam/medtronic-com/global/HCP/Documents/hvad-prod-perf-update/hvad-urgent-medical-device-notice-december-2021.pdf (accessed July 8, 2022).

[6] Meeting Summary for July 7, 2022 meeting, OPTN Heart Transplantation Committee.

status 1, 2, or 3 by exception because they generally were not hospitalized. The emergency action changed policy to allow for exception requests at the higher statuses and thus opened an avenue for these candidates to receive higher prioritization.

Background

The transplantation of adult hearts relies heavily on the use of MCSDs to bridge heart candidates to transplant. MCSD are also used as destination therapy for many individuals with heart failure.

In December 2016, the OPTN Board of Directors approved modifications to adult heart allocation policy, in part, to "reflect the increased use of MCSD and increased prevalence of MCSD complications."[7] The Briefing Paper supporting the proposed changes documented that in 2007, approximately nine percent of candidates were first registered on the waiting list using MCSD-related criteria.[8] The figure ballooned to almost 25 percent by 2015.[9] The use of MCSDs has continued growing; from October 18, 2018 through October 17, 2019, approximately 56 percent of new registrations on the adult heart waiting list had a MCSD implanted at the time of listing.[10]

The policy modifications approved by the Board of Directors in 2016 represented a substantial effort to stratify candidates based on the type of MCSD support and the risks associated with specific device complications.[11] For example, *Policy 6.1.B.iii: Mechanical Circulatory Support Device (MCSD) with Malfunction* establishes the eligibility criteria for an adult heart candidate who is experiencing a device malfunction to be assigned to adult heart status 2. A candidate experiencing pump thrombosis with their MCSD is eligible for assignment to adult status 3 based on *Policy 6.1.C.iv: Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis*. Despite the growth in the use of MCSDs and the introduction of more specific eligibility criteria for their use, current heart allocation is less specific about the appropriate status assignment for a candidate whose MCSD is the subject of a FDA recall.

Emergency Policy for Board Consideration

The policy approved by the Executive Committee modified *Policy 6.4: Adult and Pediatric Status Exceptions* by adding a pathway for transplant candidates impacted by heart device FDA recalls to pursue an exception request that does not require hospitalization as an eligibility criterion. More specifically, the policy permits a transplant program to request an exception for assignment at adult heart statuses 1, 2, or 3 for a candidate whose implanted mechanical circulatory support device, or an implanted component of the device, has been recalled by the FDA. A device recall-specific exception request does not require a candidate to be hospitalized at the transplant program where he or she is registered on the waiting list. This is a departure from prior OPTN policy where the hospitalization requirement associated with eligibility for an adult status 1, 2, or 3 exception reflects the medical urgency the heart community places on those statuses.

As part of the approved policy changes, transplant physicians are responsible for determining whether the potential clinical condition of a candidate impacted by a device recall has the urgency and potential

[7] "Proposal to Modify the Adult Heart Allocation System," OPTN Thoracic Organ Transplantation Committee, December 2016, https://optn.transplant.hrsa.gov/media/2006/thoracic_brief_201612.pdf (accessed July 7, 2022).
[8] Ibid.
[9] Ibid.
[10] OPTN Descriptive Data Request, "Two-Year Monitoring of Heart Allocation Proposal to Modify the Heart Allocation System," Prepared for Heart Committee Conference Call, March 16, 2021, Table 5: Mechanical Circulatory Support Devices at Listing for Adult Heart Candidates.
[11] "Proposal to Modify the Adult Heart Allocation System."

for benefit comparable to that of candidates assigned to adult heart statuses 1, 2, or 3. The Committee members considered whether candidates impacted by device recalls should automatically be eligible for status 2 by exception or status 3 by exception, rather than opening eligibility to the three highest priority statuses. As part of their deliberations, Committee members cited the lack of available evidence, such as waiting list mortality analyses, demonstrating that some impacted candidates should be prioritized on the waiting list ahead of others. The members agreed that without such supporting evidence, permitting access to the highest priority statuses aligned with the requirements of NOTA and the Final Rule to achieve the best use of donated organs and promote patient access. It also limited potential criticisms that the policy was arbitrarily designed. The members also indicated that any proposal must support a transplant program's ability to protect the safety of its patients. Therefore, the policy does not assign candidates impacted by a recall to a specific status, but rather leaves responsibility for determining the appropriate status with the patient's transplant physician.

Exception requests associated with device recalls follow the same process for review as other exception requests. The initial request is reviewed retrospectively by adult heart regional review boards (RRB) for approval or denial. Initial exception requests approved by a RRB result in the candidate being assigned to the requested status for 14 days. Following the initial 14-day assignment, a transplant program may request an extension of a candidate's assignment. If approved, the extension provides the candidate with up to another 14 days at the statues. There is no limit on the number of extensions a candidate may apply for (or be approved for) associated with a device recall exception.

As the Committee developed the proposal the members were deeply concerned with ensuring the new exception pathway is only available in instances where the FDA recall involves protecting patient safety from the risks of serious injury, major surgeries, or death. The Committee members pointed out that previous FDA recalls of heart devices have included components that are not surgically implanted, like battery packs. A member of the Executive Committee raised a similar question about the proposal, noting that previous emergency policies generally resulted in the changes being applied consistently to all impacted candidates; whereas, this policy did not. By developing language that specifically identifies implanted devices and implanted components, the Heart Committee sought to preclude non-life-threatening events from using the exception pathway, while also making a concerted effort not to prevent the use of an exception to address an individual circumstance that could not be captured through a more detailed or narrow set of eligibility requirements. The Committee strongly believes the proposed policy achieves that goal. At the same time, the members acknowledged that educational materials would be necessary to provide additional details about acceptable versus unacceptable uses.

Per *Policy 6.3: Status Updates*, use of the exception request process for a device recall is no longer available to a candidate whose medical condition changes and the criteria used to justify the candidate's status is no longer accurate. As such, if the recalled device is explanted, the candidate no longer qualifies for the exception. The requirement still applies that the candidate's transplant program must update the candidate's status and report the updated information to the OPTN within 24 hours of the change in medical condition.

If a RRB denies the initial exception request or any subsequent requests to extend the approved exception, the existing heart exception appeals process is available to transplant programs to pursue another review.

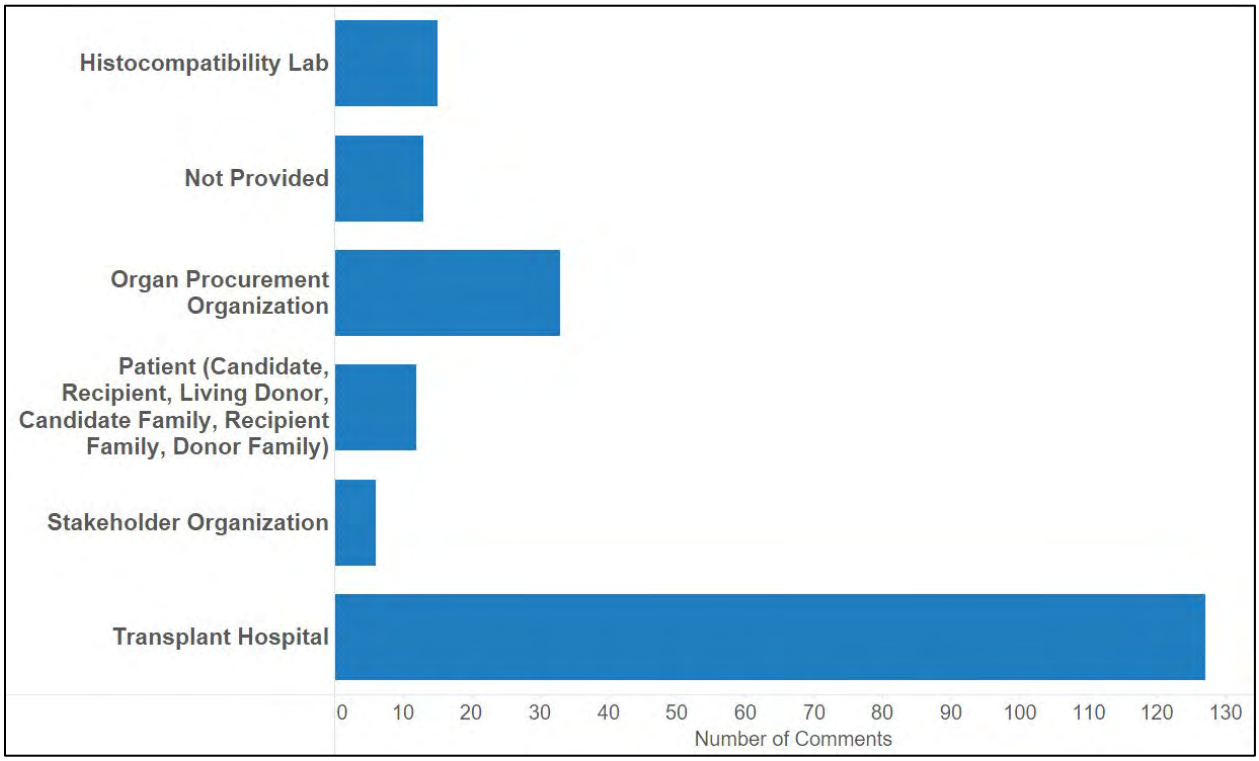
Overall Sentiment from Public Comment

The proposal was available on the OPTN website for review and public comment from August 3, 2022 through September 28, 2022. A total of 196 comments were received during that time.

Respondents were able to submit comments or indicate sentiment through: regional meetings (which included opportunities to participate both in-person and virtually), OPTN committee meetings, and a form on the OPTN website. Demographic information was collected from all respondents. Respondents at regional meetings represent the perspective of their institution, and; therefore, the demographic information associated with their sentiment also reflects the institution, rather than the individual submitting the comment. Sentiment questions were asked of online and regional respondents. The online form included open text fields for respondents to leave comments. Discussions at regional and committee meetings were summarized to collect the various perspectives voiced in those meetings.

The comments were submitted from multiple sources, as shown in **Figure 1**. Similar to other OPTN proposals, the majority of the comments and sentiment was submitted by transplant hospitals, which comprise almost two-thirds of the OPTN membership.

Figure 1: Participation by OPTN Member Type



Note: Number of comments reflects both comments and sentiment votes.

Sentiment in Public Comment

Sentiment for public comment proposals is collected along a 5-point Likert scale from strongly oppose, which is assigned a value of 1, to strongly support, assigned a value of 5. These reports are helpful to spot high-level trends but are not meant as public opinion polls or to replace the substantive analysis provided later in the document.

Generally, public comment sentiment was supportive of the policy approved by the OPTN Executive Committee in July 2022 and implemented the same month. Below are graphics that illustrate the sentiment received through public comment.

Figure 2 shows sentiment received at regional meetings. The first number in the blue circle represents the average sentiment for the policy. Using the 5-point Likert scale, the more sentiment received

supporting the proposal, the closer to 5 the average sentiment. The second number in the blue circle represents the number of sentiment votes received. Overall, regional meeting sentiment was supportive of the policy changes. As shown by the Grand Total bar, out of 175 sentiment votes received, none "opposed" or "strongly opposed" the policy.

Figure 2: Sentiment at Regional Meetings[12]

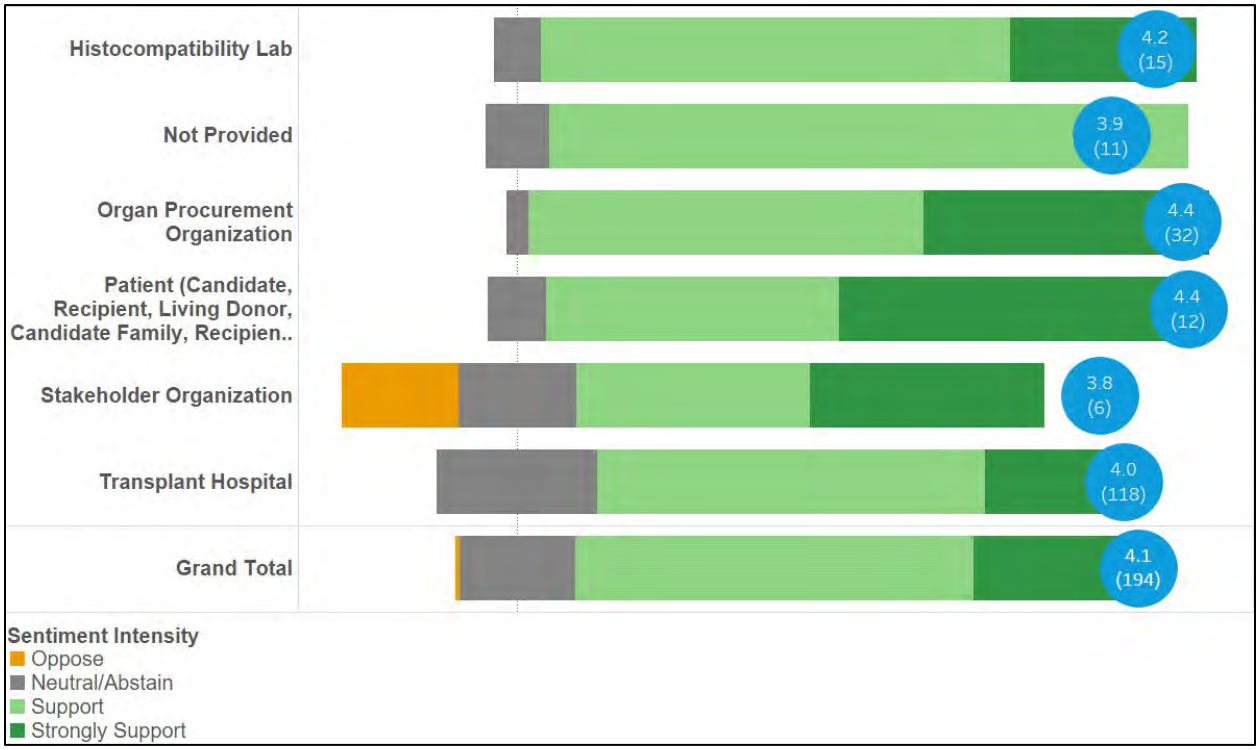
Figure 3 shows sentiment received from all respondents through the regional meetings, online, and by email reported by OPTN member type. Again, there was overall support for the concept. The volume of sentiment received by respondent is greater than the total received as part of the regional meeting because it includes online comments and comments submitted by OPTN Committees. The blue circle associated with the Grand Total bar again shows support for the policy.

Stakeholder organizations represent professional societies and organizations. Six stakeholder organizations submitted comments or sentiment about the proposal. The six are comprised of: the

[12] 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 the 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.

American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), the International Society of Heart and Lung Transplantation's (ISHLT) Advanced Heart Failure and Transplantation Interdisciplinary Network and ISHLT's Mechanical Circulatory Support Interdisciplinary Network, and NATCO. ASTS' reported sentiment was opposed to the policy.

Figure 3: Sentiment by Member Type[13]



Themes in Comments

Of the 196 responses submitted, only seven also contained a substantive, written comment.[14] This is typical since most of the responses are submitted through regional and committee meetings and this proposal was on the non-discussion agenda at regional meetings. Their comments are then summarized and submitted as one comment for the region or committee.

Commenters covered many different topics, including the following themes:

- Public comment feedback was generally supportive of the policy changes
- The OPTN Board of Directors should make the policy permanent
- Consideration should be given to increasing the number of days for the initial assignment, and any subsequent extensions

[13] 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 the 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.

[14] Public comments submitted to the OPTN website, August 3 – September 28, 2022, https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/modify-heart-policy-to-address-patient-safety-following-device-recall/ (accessed October 3, 2022).

Theme 1: Overall Support for the Policy Changes

As just discussed, there was a great deal of support for the policy. For instance, of the 118 transplant hospitals who submitted sentiment, none indicated opposition to the policy. Several of the supportive comments stressed the importance of preemptively helping candidates impacted by recalled devices. A transplant hospital stated that the proposed exception pathway "is an essential step in expediting effected candidates who have limited alternative treatment options, but risk harm and death associated due to an unsafe device." The International Society for Heart and Lung Transplantation's Mechanical Circulatory Support interdisciplinary network pointed out that the candidates who will benefit from the policy change are at imminent risk of death, which can be avoided by heart transplantation.

However, the American Society of Transplant Surgeons (ASTS) opposed the policy changes based on concerns that the "'risk' of pump stoppage is there with all [mechanical circulatory support] in principle," and that it is difficult to justify creating an exception pathway for devices that have shown no signs of failure. In ASTS' view, the new exception pathway is an opportunity for transplant programs to circumvent the clinical priorities established in existing policy. The Committee discussed the ASTS response and acknowledged that pump stoppage is inherent in devices. However, the Committee noted that a device (or device component) subject to a FDA recall related specifically to concerns about an increased risk of stoppage puts patients with such implanted devices at a greater risk for harm than devices that have not been recalled by the FDA.

Theme 2: Support for Making the Policy Permanent

The document submitted for retrospective public comment by the OPTN Heart Transplantation Committee, requested feedback as to whether the approved emergency policy changes should be made permanent policy by the OPTN Board of Directors. A total of four comments were received specifically addressing the permanency question. Three of the four recommended approval by the Board because the changes eliminate the existing hospitalization requirement in statuses 1, 2, and 3, removing a substantial barrier to the impacted candidates.

ASTS disagreed with the recommendation that the policy should be made permanent. In its response, ASTS argued that it is not appropriate to ignore the prioritization established in existing policy in order to "automatically enable" a MCS recipient who has functioning pumps and is not experiencing any issues to move to one of the three highest priority statuses. The Committee members appreciated the comment's intent to protect the priority of candidates based on actual clinical condition versus potential clinical condition. Nonetheless, the members' consensus was that making this policy permanent is important given the immediacy of the patient risks associated with device failure. The Committee reaffirmed its support for recommending to the OPTN Board of Directors that the policy be made permanent.

Theme 3: Duration of Initial Assignment and Extension

Four comments specifically addressed the questions regarding whether 14 days is the appropriate timeframe for the initial status assignment and the extension timeframe. Three of the four responses suggested extending the initial and extension timeframes beyond 14 days; with 30 days, 90 days, and an indefinite assignment being identified as alternatives. Two respondents thought the timeframes should be extended given that an individual with a recalled device faces the persistent risk of device failure until transplantation occurs. One respondent indicated that 14 days is an appropriate timeframe for assignment as part of this exception pathway.

Compliance Analysis

NOTA and OPTN Final Rule

The Committee submitted the proposal for consideration under the authority of the National Organ Transplantation Act of 1984 (NOTA) and the OPTN Final Rule. NOTA requires the Organ Procurement and Transplantation Network (OPTN) to "establish…medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria."[15] The OPTN Final Rule states that the OPTN "shall be responsible for developing…policies for the equitable allocation of cadaveric organs."[16]

The Committee submitted this proposal for the OPTN Executive Committee's consideration, acting on behalf of the OPTN Board of Directors,[17] under the authority of NOTA, which requires the OPTN to "establish…medical criteria for allocating organs and provide members of the public an opportunity comment with respect to such criteria…"[18] The Committee also submitted the proposal under the authority of the OPTN Final Rule, which states "[t]he OPTN Board of Directors shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[19] 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."[20]

As approved by the Executive Committee, this emergency policy:

- **Is based on sound medical judgment**[21] because it is an evidenced-based change relying on the medical experience and expertise of the Committee to better align candidates' medical urgency based on the candidates' clinical condition if their devices failed with the medical urgency of comparable candidates,
- **Seeks to achieve the best use of donated organs**[22] by ensuring organs are allocated and transplanted according to medical urgency. The policy is designed to ensure that candidates with implanted devices subject to a FDA recall have the opportunity to be assigned to a heart status reflecting their medically urgency if the device fails, and therefore, have increased access to a donor organ reflective of that urgency.

[15] 42 USC §274(b)(2)(B)
[16] 42 CFR §121.4(a)(1)
[17] OPTN Bylaws, *Article IV Executive Committee*, (December 6, 2021), ("Considers any issues that require expedited action between meetings of the Board of Directors.").
[18] 42 USC § 274(b)(2)(B)
[19] 42 CFR § 121.4(a)(1)
[20] 42 CFR § 121.8(a)
[21] 42 CFR §121.8(a)(1)
[22] 42 CFR §121.8(a)(2)

- **Is designed to…promote patient access to transplantation**[23] by giving similarly situated candidates equitable opportunities to receive an organ offer. Candidates impacted by a FDA device recall will have equitable opportunities to receive an organ offer based on their potential clinical condition, as determined by the transplant physician, if their implanted device were recalled.

This policy also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,[24] and it is specific to an organ type, in this case hearts.[25]

Although the approved policy addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

- **Is designed to avoid wasting organs**[26] by decreasing the number of donor hearts recovered but not transplanted.
- **Is designed to avoid futile transplants**[27] because the proposal should not result in transplanting patients who are unlikely to have good post-transplant outcomes.
- **Promote the efficient management of organ placement**[28] by taking into account the costs and logistics of procuring and transplanting organs
- **Is not based on the candidate's place of residence or place of listing**[29]

The Final Rule also requires the OPTN to "consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies" whenever organ allocation policies are revised.[30] The Committee considered whether the proposed policy changes would result in any heart population or group being treated less favorably than they would have been treated under the previous policies. The only group the Committee identified was those candidates assigned to statuses 1, 2, or 3 who might have their place on the waiting list reduced as a candidate impacted by a device recall is assigned at the same status. However, the impact of such changes is expected to be very small due to the low volume of adult heart candidates eligible to use the proposed exception pathway.

The Executive Committee is authorized to approve emergency policies according to OPTN *Bylaw 11.7: Emergency Actions*. Under Bylaw 11.7, an emergency policy is permissible if it is required due to an emergent public health issue or *patient safety factors* (emphasis added).[31] The consensus of the Heart Committee members was that an emergency action was required to address a patient safety factor associated with a recalled durable LVAD.[32] Based on the clinical factors associated with the recalls, as well as the volume of recalls, the Committee recommended that the OPTN Executive Committee approve the proposed policy modifications as an emergency action in order for the changes to be implemented as soon as possible.[33]

[23] Ibid.
[24] 42 CFR §121.8(a)(3)
[25] 42 CFR §121.8(a)(4)
[26] 42 CFR §121.8(a)(5)
[27] Ibid.
[28] Ibid.
[29] 42 CFR §121.8(a)(8)
[30] 42 CFR §121.8(d)
[31] OPTN Bylaw 11.7, *Emergency Actions* (December 6, 2021).
[32] Meeting Summary for July 7, 2022 meeting, OPTN Heart Transplantation Committee.
[33] Ibid.

Bylaw 11.7 requires that emergency policy changes designate a future date upon which the policy will expire. The future date can be no more than 12 months beyond the policy's effective date. The emergency policy became effective on July 14, 2022, and is scheduled to expire on July 13, 2023. In addition, the emergency policy must be distributed for public comment no more than six months after approval. The policy was distributed for public comment starting on August 3 through September 28, 2022. Following the retrospective public comment period, the Heart Committee prepared the policy for permanent consideration by the OPTN Board of Directors in December 2022.

In addition, the emergency policy must be distributed for public comment no more than six months after approval. The policy will be distributed for public comment on August 3, 2022.

OPTN Strategic Plan

This policy impacts the OPTN strategic plan goal to:

- *Improve waitlisted patient, living donor, and transplant recipient outcomes:*
    - The safety of waitlisted patients with implanted devices that have been recalled by the FDA is expected to improve from creation of a pathway for transplant programs to submit exception requests for adult heart statuses 1, 2, or 3 on behalf of such patients, as well as by removal of the hospitalization requirement normally associated with exceptions requests for statuses 1, 2, or 3.

Implementation Considerations

The OPTN and transplant hospitals that perform heart transplants would need to take action to implement this proposal. This proposal is not anticipated to affect the operations of histocompatibility laboratories or organ procurement organizations.

Transplant Programs

Operational Considerations

Transplant program staff need to be familiar with the circumstances under which an exception is permissible and the clinical information that should be provided in the narrative describing a candidate's condition. Transplant programs are expected to have educated staff regarding the availability of the exception request pathway associated with a device recall.

When using the exception pathway created for device recalls, transplant programs must document any materials or information associated with the recall in the candidate's medical record. The documentation must include the circumstances that support using the emergency policy.

Fiscal Impact

The policy is not expected to have a substantial fiscal impact on transplant hospitals, in part due to the small number of patients expected to be eligible for the proposed exception pathway. Transplant hospital staff need to be familiar with the circumstances by which an exception request related to a FDA device recall can be submitted, as well as the type of information that should be included in the clinical narrative supporting the request. Completion of an initial exception request and potential subsequent requests to extend a patient's assignment by exception could likely be part of standard hospital operations.

Some transplant hospitals may need to make changes to their electronic data reporting systems to account for the new data element being collected.

OPTN

Operational Considerations

The OPTN communicated the emergency policy action to all OPTN members through the use of both a pre-implementation policy notice issued on July 11, 2022 and a policy notice on July 14, 2022, and other appropriate communications on the OPTN website. In addition, OPTN members received targeted communications about the policy change as well as the implementation of the changes. Educational materials were made available on July 14, 2022.

The action required implementation in the OPTN Computer System. OPTN Waiting List documentation was revised to accommodate the creation of an exception associated with a "device recall." To utilize the exception, a transplant programs follows the existing process to indicate the status assignment request is associated with an exception. The program is then prompted to indicate whether the exception request is associated with a device recall. An affirmative response permits the request to be submitted for review even if the form indicates that the candidate is not currently admitted to the hospital. A description of the proposed new data elements can be found in **Appendix A: Proposed Data Elements and Definitions**.

Resource Estimates

This policy required 190 resource hours due to emergently implemented changes in the OPTN Computer System. The proposal resulted in implementation of data collection changes in OPTN Waiting List and communications to members about those changes. The OPTN contractor estimates 120 hours for ongoing support. Ongoing support will involve additional monitoring at 3 and 6 months, and 1 year post-implementation.

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."[34]

This proposal will not change the current routine monitoring of OPTN members. At transplant hospitals, site surveyors will continue to review a sample of medical records, and any material incorporated into the medical record by reference, to verify that data reported in the OPTN Computer System to justify a candidate's status are consistent with documentation in the candidate's medical record.

[34] 42 CFR §121.8(a)(7)

Policy Evaluation

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate."[35] This policy will be formally evaluated at approximately 3 months, 6 months, and 1 year post-implementation. The following metrics, and any subsequently requested by the committee, will be evaluated as data become available (Appropriate lags will be applied, per typical OPTN conventions, to account for time delay in institutions reporting data) and compared to an appropriate pre-policy cohort to assess performance before and after implementation of this policy, where appropriate. Timeline is subject to change based on the results. Data will be presented in tabular and graphical form as appropriate.

The following metrics and any others subsequently requested by the Committee, will be evaluated:

- The number and percent of all registrations that submitted a 'device recall exception'
- The number and percent of registrations ever waiting by medical urgency status and criteria within medical urgency status (including 'device recall exception')
- The number and percent of waitlist additions by medical urgency status and criteria within medical urgency status (including 'device recall exception')
- The number and percent of waitlist additions by medical urgency status and criteria within medical urgency status (including 'device recall exception') and by month
- The number and percent of transplants by medical urgency status and criteria within medical urgency status (including 'device recall exception')

Conclusion

The emergency policy developed by the OPTN Heart Transplantation Committee and approved by the OPTN Executive Committee addresses an emergent need to protect the patient safety of certain adult heart transplant candidates who are impacted by FDA-issued recalls of their implanted devices.

The changes permit a transplant program to request an exception for an adult heart status 1, 2, or 3 in the event that a transplant candidate's implanted MCSD, or a component within the MCSD, is subject to a recall by the FDA, even if the candidate is not hospitalized at the time. The candidate's transplant physician must determine that the MCSD is a risk to patient safety that cannot be sufficiently mitigated without replacement of the device. The Committee's intention is for the new pathway to protect the safety of those whose devices have been recalled, but remain clinically stable.

[35] 42 CFR §121.8(a)(6)

Policy Language

Language that is proposed for extension is in italics (*example*)

6.4 Adult and Pediatric Status Exceptions

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

Table 6-3: Exception Qualification and Periods

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
Adult status 1	1. Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and 2. Transplant physician believes, using acceptable medical criteria, that the heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	RRBs retrospectively review requests for status 1 exceptions	14 days	• Require RRB approval for each successive 14 day period • RRB will review and decide extension requests retrospectively
Adult status 2	1. Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and 2. Transplant physician believes, using acceptable medical criteria, that the heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	RRBs retrospectively review requests for status 2 exceptions	14 days	• Require RRB approval for each successive 14 day period • RRB will review and decide extension requests retrospectively
Adult status 3	1. Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and 2. Transplant physician believes, using acceptable medical criteria, that the heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	RRBs retrospectively review requests for status 3 exceptions	14 days	• Require RRB approval for each successive 14 day period • RRB will review and decide extension requests retrospectively

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
Adult status 1, 2, or 3	*1. Candidate's implanted mechanical circulatory support device, or an implanted component within, has a U.S. Food and Drug Administration recall that the transplant physician determines is a risk to patient safety that cannot be sufficiently mitigated without replacement of the device or the component, and* *2. Transplant physician believes, using acceptable medical criteria, that the heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status*	*RRBs retrospectively review requests for exceptions associated with a heart device recall*	*14 days*	• *Require RRB approval for each successive 14 day period* • *RRB will review and decide extension requests retrospectively*
Adult status 4	Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	RRBs retrospectively review requests for status 4 exceptions	90 days	• Require RRB approval for each successive 90 day period • RRB will review and decide extension requests retrospectively
Pediatric status 1A	• Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and • Transplant physician believes, using acceptable medical criteria, that the heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	The national heart review board (NHRB) retrospectively review requests for Status 1A-exceptions	14 days	• Require the NHRB approval for each successive 14 day period • The NHRB will review and decide extension requests retrospectively

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
				• If no extension request is submitted, the candidate will be assigned pediatric status 1B
Pediatric status 1B	Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	The NHRB retrospectively review requests for Status 1B exceptions	Indefinite	• Not required as long as candidate's medical condition remains the same

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Appendix A: Proposed Data Elements and Definitions

The Committee determined that a new data element will need creating to capture if the exception request is associated with a heart device recall issued by the United States Food and Drug Administration.

Data Element	Current Definition	Proposed Definition
This exception request is specifically related to a device recall	This is a new data element	Candidate does not meet any of the criteria above but has an urgency and potential for benefit comparable to that of other candidates at the status and is either admitted to the transplant hospital that registered the candidate on the waiting list, or candidate's implanted mechanical circulatory support device, or an implanted component within, has a U.S. Food and Drug Administration recall that the transplant physician determines is a risk to patient safety that cannot be sufficiently mitigated without replacement of the device or the component.

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