OPTN Heart Committee
Meeting Summary
September 22, 2023
Detroit, MI

Rocky Daly, MD, Chair
J.D. Menteer, MD, Vice Chair

Introduction

The OPTN Heart Committee ("Committee") met in Detroit, MI on 09/22/2023 to discuss the following agenda items:

1. Amend Adult Heart Status 2 Mechanical Device Requirements Policy Proposal
2. Overview of Organ Allocation Simulation Modeling
3. Continuous Distribution of Hearts Concept Paper
4. Finalize Attributes for Values Prioritization Exercise
5. Efficiency Task Force Overview
6. Develop Rating Scale for Medical Urgency
7. Develop Rating Scale for Blood Type

The following is a summary of the Committee's discussions.

1. Amend Adult Heart Status 2 Mechanical Device Requirements Policy Proposal

The Committee reviewed their proposal which received public comment "Amend Adult Heart Status 2 Mechanical Device Requirements".

Data summary:

The Committee discussed their proposal related to intra-aortic balloon pump (IABP) criteria and percutaneous endovascular mechanical circulatory support device for adult Status 2 patients. The proposed policy suggests that patients must fail inotropic support before becoming eligible for balloon pump and Status 2 listing. Public comment for this proposal has generally been favorable, however concerns have arisen regarding the potential for arrhythmias when using inotropic support and the criteria for determining failure. Stakeholder organizations generally supported the proposal but suggested defining the duration of inotropic therapy and considering Status 2 for patients unable to tolerate high-dose inotropes.

Public comment on the proposal has closed, and the sentiment score for the proposal remains at 3.5, indicating moderate support. The breakdown of sentiment scores by region shows that there were 30 strongly supportive, 103 supportive, and 88 neutral/abstain responses. Thirteen respondents opposed the proposal, and 13 strongly opposed it.

Summary of discussion:

The OPTN contractor discussed the role of logical outgrowth when considering potential changes, and clarified how post-public comment changes might require further public comment if they are not a logical extension of the original proposal. A member wondered if the policy should have increased specificity for the duration of inotropic therapy. Several public comments were highlighted, including questions from Region 2 and an anonymous commenter regarding how long a patient should be trialed

on inotropes before temporary mechanical support is provided. Region 2 also raised concerns about the clinical parameters used to classify someone as sick while on inotropes. The Chair acknowledged the complexity of defining a specific timeframe for inotropic therapy, given that patients can vary in their response to treatment. The consensus was that prescribing a rigid time limit doesn't align with the clinical reality of patient care. It was emphasized that the decision to escalate care should be based on clinical judgment and the patient's condition. A member highlighted again that the proposal aimed to ensure that patients demonstrate a genuine need for temporary mechanical support before receiving it. They added that they did not want the proposal to be too prescriptive, as this might generate a significant number of exception requests. It was suggested that incorporating clinical indicators like lactate or creatinine levels could provide a more objective basis for determining when inotropic therapy has failed and when mechanical support is warranted. This approach would require consecutive readings to demonstrate a lack of improvement in the patient's condition.

A member considered the potential consequences of imposing a specific time parameter for inotropic therapy. It was noted that such a parameter might lead centers to merely "check the boxes" without genuinely assessing a patient's condition. One member pointed out that medications like epinephrine work in seconds to minutes, making it unnecessary to specify a time frame. The focus should be on meeting hemodynamic criteria rather than adhering to a rigid time limit. The consensus among members was that leaving the policy without a strict time parameter encourages clinical discretion and ensures patient safety. Members remained split about the inclusion of a specific time parameter for inotropic therapy. Some members expressed concerns about the impact on exception requests, while others believed that without a time parameter, OPTN members may attempt to continue to exploit the system. They noted the potential for patients to undergo a brief inotropic therapy session solely for the purpose of maintaining Status 2. Concerns were raised about the integrity of the system and the need to avoid creating loopholes that could be exploited. However, it was recognized that making a substantial change to the policy may not be feasible at this time.

One member proposed including a minimal time requirement, such as one or two hours, for inotropic therapy before qualifying for Status 2. The argument was that even a minimal time requirement could discourage unnecessary use of balloon pumps and promote genuine clinical assessments.

Additionally, there was a brief discussion about the possibility of moving balloon pump criteria to Status 3, but it was noted that this would require further consideration due to the broader scope of the proposal and would not be considered logical outgrowth.

There was a suggestion to consider allowing patients who do not meet specific inotropic criteria to transition to Status 3 if they receive a temporary mechanical support device. This could provide an alternative pathway for such patients and potentially reduce the number of exception requests. The Chair stressed the importance of not separating balloon pumps from other temporary mechanical circulatory support (MCS) devices. Doing so might raise concerns about potential financial incentives and costs associated with different MCS devices. It was emphasized that the proposal covers all temporary mechanical devices and avoids creating disparities.

Following a question on extension requests, a member clarified that the proposal required patients on a balloon pump to still be supported throughout the time of their initial assignment by the same inotropic therapy, which means they would need to wean off the balloon pump, reinstitute inotropes, and demonstrate a lack of improvement to qualify for an extension.

The Committee also considered the possibility of patients remaining in Status 2 for up to 14 days without clear guidance on their clinical management during that time. There was a suggestion that the policy should explicitly state that patients should continue to meet the criteria during those 14 days.

The discussion also touched on the broader goals of the policy, which were to strike a balance between minimizing disruptions to the system and addressing the issue of patients being listed as Status 2 without a clear clinical need.

The Committee returned to discussing the rationale behind not specifying a time frame for inotropic therapy in the proposed policy. One key reason that emerged during drafting for this decision was the need to create the policy quickly and align it with existing parameters to facilitate easy implementation. The lack of available data to support a specific time frame was also a contributing factor, as the Committee recognized that choosing any arbitrary number could be contentious without sufficient data. The sentiment among Committee members was that the primary focus should be on ensuring that patients genuinely met the criteria for Status 2 based on clinical conditions, rather than rigidly prescribing a time frame. The goal was to avoid creating a policy that would be criticized for its lack of data-driven decision-making.

The Chair asked that members who did not agree with the Committee's position share their opinions. It appeared that most members were inclined to proceed without a specific time duration requirement, as they considered other factors, such as supply shortages and the complexity of individual patient cases.

One member emphasized the importance of aligning the policy with the evaluation plan for program reviews, ensuring that survey teams understand the criteria and do not inadvertently apply an inappropriate time frame during assessments.

The Committee continued discussing the proposal, and suggested the need for more regional review board (RRB) guidance, particularly regarding arrhythmias in the context of inotropes and mechanical device support. It was acknowledged that existing guidance related to arrhythmias should also be further refined. One of the primary points of discussion was defining criteria for arrhythmias that would qualify patients for Status 2. The focus was on ventricular tachycardia (VT) and the need for a clear definition. A proposed definition included sustained VT greater than 30 seconds, which appears in status 4 policy, or VT requiring cardioversion, provided that normal electrolyte levels were maintained and the patient was on inotropic therapy. This definition aimed to strike a balance between specificity and clinical relevance. There was also a suggestion to include considerations for unstable atrial arrhythmias and create a guidance document that outlined these criteria. The goal was to establish a set of clear criteria that would help in determining when patients experiencing arrhythmias would qualify for Status 2. The inclusion of unstable atrial arrhythmias was considered, but the consensus leaned towards excluding them from the policy and handling them as exception requests.

The importance of safety was emphasized repeatedly, with concerns raised about putting patients at risk by encouraging the development of arrhythmias through inotrope administration. Multiple members agreed that any criteria should prioritize patient safety and clinical appropriateness. The importance of including cardioversion as part of the criteria for arrhythmias was emphasized to ensure patient safety. The Committee agreed to refine the wording and circulate it for review before the next meeting in October, where they would vote on the updated policy.

A member asked whether these criteria should be included in the policy or in a guidance document. Members felt that these criteria should be integrated into the existing policy rather than creating a separate document.

<u>Next steps:</u>

The Committee will vote on final language at their following meeting.

2. Overview of Organ Allocation Simulation Modeling

The Committee heard a presentation on the modeling for Heart continuous distribution.

Presentation Summary:

The Scientific Registry of Transplant Recipients (SRTR) representative introduced the simulation and its application in the context of organ allocation. The presentation focused on the fundamental principles of simulation and its role in generating data for organ allocation policy evaluation.

- The SRTR representative provided an overview of the organ allocation system, emphasizing the critical role of allocation rules in determining which candidates receive organs
- They emphasized that simulation modeling requires simplification due to the complexity of the organ allocation system. Data collection starts with candidates and donors, and the analysis focuses on the allocation of donated organs based on established rules.
- They explained that simulation is employed because specific data for alternative allocation policies does not exist. It allows researchers to create counterfactual scenarios and generate data about potential allocation policies.
- They outlined how sub-models contribute to the simulation analysis by creating novel scenarios, increasing variability, and simulating outcomes for candidates and donors.
    1. History Generation Model: Generates candidate histories to account for transplants, deaths, or removals.
    2. Randomized Arrivals Model: Shuffles donor arrivals to introduce variability.
    3. Placement Mechanism Model: Determines which candidate receives an organ.
    4. Post-Transplant Survival Model: Models post-transplant survival for recipients.
    5. Failed Graft and Relisting Models: Addresses candidates who experienced failed grafts, relisting, and potential retransplants.

The presentation provided the committee with an overview of simulation in organ allocation analysis, highlighting its purpose, components, and relevance in studying allocation policies. The presentation concluded by emphasizing the need for simplification and data generation to address specific research questions related to organ allocation.

Summary of discussion:

A member raised a question regarding the limitations of simulation models in accounting for real-world factors and variables that can influence the organ allocation system. The concern was that real-world complexities might not be fully captured in simulations, potentially leading to discrepancies between simulation outcomes and actual outcomes. For instance, a patient's refusal to undergo a required cardiac catheterization could result in their removal from the waiting list. The presenter acknowledged that no model can be entirely perfect due to the inherent complexities of the real world. However, they noted that part of the process in building the simulation model is considering these real-world factors and uncertainties during the development of specific sub-models within the simulation. Furthermore, by using statistical models in cases where specific real-world events or decisions are difficult to replicate, the typical behaviors and decisions observed in real-world scenarios are possible to observe in aggregate.

The STRT representative concluded by noting that while simulations are valuable tools for policy evaluation, they cannot fully replicate every real-world scenario. Instead, they aim to capture broad

trends and patterns to inform decision-making. The process will be iterative and will require fine-tuning once implemented.

Next steps:

3. Continuous Distribution of Hearts Concept Paper

The Committee discussed their concept paper on the Continuous Distribution of Hearts.

Presentation Summary:

1. Post-Transplant Survival Consideration
2. Data Challenges and Predictive Complexity
3. Balancing Utility and Complexity
4. Conditional Outcome Consideration
5. Complexity and Data Collection Challenges
6. Immediate Prioritization

Summary of discussion:

Members engaged in a robust discussion regarding the inclusion of post-transplant survival as an attribute within the concept paper for continuous distribution (CD) of donor hearts. In this debate, concerns arose regarding the availability of sufficient data and statistical power to accurately integrate this attribute into the model. However, members acknowledged the inherent challenges in obtaining reliable post-transplant survival data. Predicting outcomes over several years is a complex task due to various factors, including patient selection, evolving medical conditions, and surgical biases.

A member underscored the need to strike a balance between including clinically relevant attributes for informed decision-making and maintaining a manageable and interpretable model. There was a consensus that adding too many attributes could potentially dilute their impact. Some members felt that, if post-transplant survival were to be incorporated, the model should also account for conditional outcomes. For instance, survival outcomes for patients who have already surpassed a specific post-transplant period might differ from the general population.

Another member expressed reservations about the complexity associated with long-term outcome predictions and the practical challenges of gathering pertinent data. It was suggested that this issue might be more effectively addressed in future iterations of the framework with enhanced data availability and advanced statistical methods. Given the current complexities and data limitations, there was consensus among members to prioritize other attributes and components of the CD model over post-transplant survival during the initial iteration. While there was recognition of its potential utility, the Committee leaned toward postponing its inclusion to future iterations when data availability and analytical methods may be better equipped to address this complex aspect.

The Committee then addressed the consideration of size matching as a relevant factor. A summary of the viewpoints expressed is below:

- **Clinical Relevance**: The relevance of size matching was discussed, particularly for pediatric patients and individuals with distinct size needs. While some members argued that size matching was crucial for these cases, others questioned its applicability for adult candidates.
- **Data Availability**: Committee members aligned on the need to gather data on waiting times, waitlist mortality rates, transplant rates, and other factors related to size matching to make an informed decision on its inclusion.

While post-transplant survival was not favored for inclusion in the 1st iteration of the model due to data limitations and potential complexities, the Committee expressed an interest to consider an attribute to prioritize candidates for whom it is difficult to find a suitable donor organ because of their stature (big or small) in subsequent discussions, especially for pediatric patients and other populations with unique size requirements.

Next steps:

The Committee will discuss size matching at their subsequent meeting.

4. Finalize Attributes for Values Prioritization Exercise

An overview of the Values Prioritization Exercise was presented, along with attribute descriptions.

Presentation summary:

The Committee discussed the importance of clarifying and refining these descriptions to ensure they are clear, understandable, and meaningful to the broader community.

1. Values Prioritization Exercise:

- **Purpose:** The Values Prioritization Exercise aims to collect feedback from a diverse community, including patients, families, and the public, regarding the relative importance of various attributes when allocating hearts. It is a values-driven exercise and does not rely on existing data.
- **Comparative Assessment:** Participants in the exercise are asked to compare pairs of attributes (e.g., medical urgency vs. pediatric priority) and indicate which one they find more important. This process helps gauge community preferences.
- **Attribute Clarity:** The committee emphasized the importance of providing clear and accessible descriptions of attributes to ensure that participants understand what they are comparing. The goal is to avoid any potential confusion among the public.

2. Attribute Definitions:

- **Feedback Sought:** Committee members were asked to review and provide feedback on the descriptions of attributes presented during the meeting. These descriptions are meant to help the public understand the attributes in question.
- **Clarifying the Exercise's Purpose:** Committee members emphasized that the exercise is intended solely to gather feedback from the community and that the descriptions should not be interpreted as definitive or prescriptive for the allocation policy. The goal is to capture community perspectives.
- **Public Understanding:** The descriptions aim to make complex attributes comprehensible to a broad audience. Definitions should strike a balance between simplicity and accuracy to facilitate meaningful feedback.

Summary of discussion:

A member stressed the need for attribute descriptions to be straightforward and comprehensible to individuals outside the field of cardiology, including politicians and the general public. The descriptions should provide basic but meaningful structure to help participants in the exercise make informed choices. A second member agreed, and added that the wording of hypothetical cases should be simple and accessible. For instance, explaining what is meant by "highly sensitized" and other attributes.

A member wondered if some questions about specific attributes, such as the timeframe of "3 years" for a candidate waiting, would necessarily be confusing as members of the public would not have context

for how long or short this was. It was reiterated that the exercise's purpose is to gather feedback from the community, and the attribute descriptions are not intended to dictate policy but rather to make complex concepts understandable. In addition, the Chair felt that when compared two hypothetical candidates, the concept of different wait times, e.g. one has three years and the other has six months, would be understood.

The Committee reaffirmed the purpose of the exercise as collecting community perspectives rather than dictating allocation policy. Members generally agreed that the descriptions were adequate for the exercise's intended purpose.

Next steps:

The Committee will review the final attributes that will be proposed at a subsequent meeting.

5. Efficiency Task Force Overview

Staff presented on the Task Force to address allocation efficiency.

Presentation Summary:

Member quality staff provided information about the Efficiency Task Force, which was established to address issues related to patient allocation efficiency. The presentation covered several key points:

1. Background:

- The Efficiency Task Force was initiated after discussions at a previous board meeting.
- The task force has been gathering data and insights on allocation efficiency since its launch.

2. Challenges in Allocation Efficiency:

- Allocation efficiency is a multifaceted challenge involving various factors such as policy implications, federal requirements, operational inefficiencies, logistical issues, and behavioral aspects.
- Inefficiencies in allocation can lead to increased organ non-use, a problem that is worsening over time.
- Changes in allocation policies, such as for kidneys and livers, have sometimes led to allocations out of sequence, complicating the issue.

3. Purpose of the Task Force:

- The task force aims to increase efficiency in organ allocation and improve allocation strategies.
- It emphasizes greater communication and collaboration with the transplantation community.
- Pilot projects will be initiated to test potential solutions and gather data to inform decisions.
- The task force will explore various options, including policy changes, data collection, and standardization of processes.

4. Task Force Responsibilities:

- The task force will review existing data, recommendations, and reports related to allocation efficiency.
- Engagement with the transplantation community, including committees, is a priority, involving surveys, interviews, focus groups, and webinars.
- The task force will prioritize short-term improvements and develop plans for more complex, long-term challenges.
- Regular updates will be provided to the executive committee and the board of directors.

5. Implications for Other Committees:

- The formal governance structure for committees remains unchanged.
- Committees will continue their work within their scopes, but they are encouraged to support the task force by providing feedback and recommendations.
- Committees can also forward issues to the task force that align with allocation efficiency goals.
- Participation in task force community discussions, webinars, town halls, and focus groups is encouraged.

6. Committee's Role:

- Committees are requested to review their current projects and assess whether they align with efforts to improve allocation efficiency.
- Policy projects and ideas related to allocation efficiency should be prioritized, and collaboration with the task force is encouraged.

Summary of discussion:

A member sought clarification on what "efficiency" meant in the context of organ allocation. They wanted to understand the specific aspects of allocation efficiency the task force would address. Staff replied that it would holistically consider aspects of efficiency such as non-utilization of organs and transportation.

A member inquired about how the work of the Committee, particularly in areas like continuous distribution and distance factors, might align with or coexist with the task force's objectives. The presenter responded that the goals of the task force would align with the Committee, especially as they consider the values prioritization exercise and the weight of distance.

Members highlighted the importance of collecting data related to heart allocation issues and mentioned challenges like non-utilization of organs and the impact of appeals on allocation decisions. However, concerns were raised about the perceived power of appeals in organ allocation and the potential impact on the efficient placement and utilization of organs.

The Committee also discussed various complex allocation issues, such as logistical challenges, time constraints, and the need to honor families' wishes in the organ donation process. A member noted that there is often difficulty in ascertaining when time constraints will arise and whether OPOs or transplant programs are responsible for these timeframe changes. The need for a balance between efficiency and patient considerations, including honoring donors' families and working with multiple surgeons, was emphasized.

The Committee appreciated the effort of the OPTN to establish this task force and acknowledged the importance of addressing allocation efficiency issues. They also expressed the need for a comprehensive approach that considers various factors impacting organ allocation, such as organ quality and time frame considerations. They welcomed the task force's formation and expressed their commitment to providing input and data to support its efforts.

Next steps:

The Committee will review its existing projects to determine if any should be prioritized per the task force request.

6. Develop Rating Scale for Medical Urgency

The Committee reviewed the rating scale for medical urgency.

Presentation Summary:

- **Objective of Transition**: The primary objective of the discussion was to determine if the committee agreed with the idea of shifting the current statuses onto a continuous scale. This transition involved initially grouping the criteria within each status on the continuous scale and then evaluating whether certain criteria should be separated. If so:
    - **What should be the scale shape**: The two main considerations were whether the scale should be linear or exponential and how steep the gradient should be. The choice of scale shape would have a significant impact on how candidates' medical urgency is assessed.
    - **Definition of Medical Urgency**: The committee clarified that the focus of this discussion was on the medical urgency aspect of organ allocation. It was emphasized that candidates would receive points based on their medical criteria, including waitlist mortality, blood type, sensitization, and other medical attributes.

Data was presented from the 3-year monitoring report to support the concept of a continuous distribution scale. The data demonstrated the differences in mortality rates among status levels. The Committee considered how candidates might be ranked based on mortality rates, and the impact of different scale shapes, including exponential and linear.

Summary of discussion:

The Committee discussed the idea of transitioning to a continuous distribution scale for organ allocation, where each status would initially be grouped together based on criteria. The use of statuses as discreet classifications would be replaced by a continuous scale, making it easier for the community to understand. A member wondered whether candidates should be ranked based on medical criteria other than those currently used (e.g., the type of pump they are on). The challenge discussed was how to separate candidates once they are on a pump if their medical condition improves.

The Committee also discussed the need to differentiate between different statuses (e.g., statuses 2 and 6) on the rating scale. There was a consideration of assigning different percentages of points to statuses to achieve this differentiation. The Chair reiterated that the focus of this discussion was on the medical urgency aspect of organ allocation. It was emphasized that candidates would receive points based on their medical criteria, including waitlist mortality, blood type, sensitization, and other medical attributes.

The proposed approach involved initially grouping candidates of the same status together on the medical urgency scale. However, it was noted that these criteria could eventually be separated based on data and evidence. A member suggested that a linear or gradual gradation approach was suggested to avoid drastic differences in medical urgency points. A second member supported this, highlighting the importance of data in making informed decisions. Waitlist mortality rates were examined as a basis for assigning urgency points, but concerns were raised about its limitations in reflecting true medical urgency when candidates improve or change status. The Committee questioned whether the data accounted for changes in a candidate's status over time. Staff replied that the data considered changes in status, particularly at the time of transfer between statuses.

Concerns were raised about the similarity in waitlist mortality rates between patients with balloon pumps (status 2) and patients on percutaneous support (status 3). The Committee acknowledged the need to differentiate these cases based on their true medical condition and urgency.

The Committee recognized that the policy should accurately reflect the medical urgency of candidates. It was noted that the policy had previously addressed some of these issues by prioritizing patients who became status 2, leading to differences in waitlist mortality between statuses.

A member highlighted the need for a significant point gap to ensure candidates' rankings remain consistent across statuses, especially when other attributes come into play. It was suggested that a linear scale might not be suitable for this purpose. Some members proposed an intermediate scale with varying gaps between statuses. This approach aimed to balance the need for differentiation with practicality. The idea was to create a scale that reflects medical urgency but avoids overly drastic differences in points. However, the Committee recognized the need for mathematical expertise to fine-tune the continuous scale in the future. A member noted the importance of mathematicians to optimize the distribution of candidates on the scale based on data.

A question was raised about whether it makes sense to combine status 5 and 6 due to their overlapping mortality rates. The concern was whether the distinction between these statuses was necessary or if they could be collapsed into a single category. Members felt that this could be an option but would need to be informed by data.

It was noted that future policy changes might influence how dual organ recipients are prioritized and that, for now, it's essential to consider the existing distinctions.

A member wondered whether inactive time should be included in mortality calculations and whether deaths occurring during inactive periods should be attributed to the patient's status at the time of listing or the status at the time of death.

The Committee reaffirmed that the criteria currently used to define statuses would be a starting point for the transition. The intention was to initially place candidates on the continuous scale based on these criteria and then refine the distribution over time.

The Committee also considered how pediatric patients would need to be addressed when considering medical urgency in continuous distribution. Members addressed the need to collect specific data regarding congenital heart disease and other pediatric conditions to ensure accurate status assignment and allocation. They discussed the importance of defining these conditions clearly and consistently to aid in data analysis and future refinement of the allocation system. The Committee recognized the value of studying exception requests to identify patterns or criteria that might not be adequately captured in the existing allocation policy and creating accurate definitions in new policy. This information could further help refine the allocation criteria in the future.

When considering a system where pediatric and adult patients could be integrated, allowing for a seamless allocation process, a member introduced the concept of "1A+" for pediatric patients. This

would aim to ensure that pediatric status 1A patients could attain a similar level of urgency as adult status 1 patients while retaining the urgency of pediatric need. This was achieved by assigning similar points to these categories. A second member suggested subdividing pediatric status 1A into multiple levels, each reflecting varying levels of urgency. These levels would be designed to distribute patients based on medical urgency, with consideration for factors like ventricular assist devices (VADs) and other criteria. The Committee acknowledged the high waitlisted mortality in pediatric patients, especially at higher urgencies. Addressing this issue and optimizing pediatric wait times was recognized as a separate project that needed further consideration.

Next steps:

The Committee will continue to determine how medical urgency should factor into continuous distribution. Further work was planned to refine the allocation criteria and address waitlisted mortality issues specific to pediatrics.

7. Develop Rating Scale for Blood Type

The Committee reviewed creating a rating scale for blood type for continuous distribution. This was done to recognize certain blood types might have potential disadvantages to receiving organ offers compared to others.

Presentation Summary:

- **Data Analysis**: Data was presented to the committee, showing the breakdown of candidates by blood type and the number of eligible donors for each blood type. Eligible donors referred to identical blood types as well as compatible blood types.
- **Scaling the Blood Group Attribute**: The Committee considered how to scale the blood group attribute. Initially, the data showed a greater ratio of candidates to donors for blood type A, indicating potential disadvantages for other blood types.

Summary of discussion:

The Committee discussed the design of the initial scale for the blood group attribute. The proposal included using a bar graph and allocating points based on blood type, with blood type O receiving the most points and other blood types receiving fewer points. Some committee members raised concerns about blood type disparities and suggested that blood type O should receive 100% of the points as O donors have the greatest competition among compatible recipients. They also proposed that blood type A and blood type B should receive fewer points to reflect the donor ratios. A member asked whether AB blood group should receive points or be considered as a tie-breaker. There were varying opinions on how AB blood type should be factored into the allocation system, as some members felt that AB blood group candidates' ability to receive any organ should not amount to any points, while others noted then the difficulty in prioritizing AB blood type candidates.

The Committee briefly discussed how incompatible blood types should be addressed in the allocation system, ensuring that they do not receive organs from incompatible donors. Members wanted the system to be designed to provide as much safety as possible while still ensuring all potentially usable offers are received by candidates.

Concerns were raised about the potential impact of medical urgency and other factors on the allocation of points for blood group. Staff noted that while the committee can propose a specific point system, the overall system design may have different priorities depending on how modeling details the prioritization. Members agreed that further modeling and considerations were needed to determine the final allocation point system for blood group attributes.

The committee discussed a recent proposal from the OPTN Lung Committee, which suggested allocating points for blood group compatibility. Some members expressed concerns about the disparity in points allocation in Lung Committee's proposal, with blood type O receiving 100% of the points and other blood types receiving lower percentages. Members considered the historical data related to transplant rates for blood types A and B to determine if one should be prioritized above another. The data showed some variation, but overall, A and B appeared to be relatively similar. Several members suggested that blood types A and B should be grouped together, but receive points differently when receiving offers with donor blood type O. A member restated that blood type O should receive all the points, while A and B would receive some fraction of those points.

A member asked how to handle intended incompatible blood types in the allocation system. Another member proposed assigning them zero points in those offer situations. It was suggested that this would be a good issue to simulate and model to determine the most suitable scale for the blood group attribute and intended incompatibility.

Members considered the question of sensitization. Sensitization refers to candidates becoming immunologically reactive to certain donor tissues, limiting their potential matches. Several members noted that the need to prioritize highly sensitized candidates should be discussed. There was agreement that an exponential scale should be used; however, members were split on how severe the scale should be. One member suggested that highly sensitized candidates (above 80%) should receive all points, while another suggested a flatter curve, where points start at 50% but candidates will not receive full points until higher than 80% sensitization. A member also mentioned that candidates below 50% sensitization should not get points. A second member noted that the decision to use a 50% sensitization threshold for candidates to start receiving points was supported by data showing increased risk of removal from the waitlist for candidates with a CPA over 50%. It was suggested that the curve should be steep above 80%, with candidates getting sharply more points as sensitization increases past that point.

The Chair emphasized the importance of including sensitivity in the model and determining the shape of the distribution curve for allocation points. The Committee was aligned that higher allocation points would be given to higher medical urgency patients, but expressed a need for further data to support how those points are distributed. It was emphasized that modeling could help shape the curve to align with the Committee's goals.

Members expressed concerns about the process of exception reviews, emphasizing the need for clear guidelines and structure for writing exception letters. They discussed the importance of providing feedback to review board members and suggested regular meetings or communications to improve consistency and quality in exception approvals.

The Committee briefly discussed the question of out of sequence allocation. It was mentioned that expedited placements usually occur when there is a time constraint or a need to maximize organ placement. The decision to expedite is influenced by factors like cold ischemic time and family requirements. A member noted that it frequently felt like there was a lack of clarity surrounding when a recovery would be expedited. A second member expressed that it's often a difficult timeline to predict and highlighted that it's not about holding families hostage but rather working with them to optimize organ placement. They felt that frequently there was a misconception that Organ Procurement Organizations could choose their timelines freely.

A member brought up the concept of expedited allocation for kidneys and wondered if any parallels could be useful to the Committee. They considered that it often occurs when there's a significant amount of cold ischemic time. This influences transplant programs to be less likely to accept the organ.

Several members replied to this and expressed the need to incorporate efficiency into the continuous distribution model and improve the allocation process for various organs.

Noting that the meeting had reached its planned end time, the Chair thanked members for attending and requested the discussion be continued in subsequent meetings.

Next steps:

The Committee will review the modeling results for point allocation in different blood type and sensitization curves. They will also consider the need for efficiency in the continuous distribution format.

Upcoming Meeting

- October 4, 2023
- October 17, 2023
- November 1, 2023
- November 21, 2023
- December 6, 2023
- December 19, 2023

Attendance

- **Committee Members**
  - Rocky Daly, Chair
  - J.D. Menteer, Vice Chair
  - Tariq Ahmad
  - Tamas Alexy
  - Amrut Ambardekar
  - Kim Baltierra
  - Jennifer Carapellucci
  - Jen Cowger
  - Tim Gong
  - Eman Hamad
  - Jennifer Hartman
  - Glen Kelley
  - Earl Lovell
  - Cindy Martin
  - Nader Moazami
  - John Nigro
  - Fawwaz Shaw
  - Cristina Smith
  - Martha Tankersley
  - Dmitry Yaranov
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Yoon Son Ahn
  - Katie Audette
  - Monica Colvin
  - Grace Lyden
  - Tim Weaver
- **UNOS Staff**
  - James Alcorn
  - Alex Carmack
  - Cole Fox
  - Ann Marie Leary
  - Isaac Hager
  - Kelsi Lindblad
  - Alina Martinez
  - Eric Messick
  - Holly Sobczak
  - Kim Uccellini
  - Sara Rose Wells
- **Other Attendees**
  - Stephanie DeLair
  - Shelley Hall
  - Ted Papalexopoulos
  - Stephanie Taylor