OPTN Kidney Transplantation Committee
Meeting Summary
March 18, 2024
Teleconference

Jim Kim, MD, Chair
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Introduction

The Kidney Transplantation Committee (the Committee) met via teleconference on 3/18/2024 to discuss the following agenda items:

1. Executive Committee: Strategic Plan Proposal
2. Defining Hard to Place: Clinical Definition

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

1. Executive Committee: Strategic Plan Proposal for Public Comment

A representative from the OPTN Executive Committee presented the Executive *Committee's OPTN Strategic Plan 2024-2027* proposal, and the Committee provided feedback.

Presentation summary:

The OPTN Board of Directors adopts a new strategic plan every three years; the current plan expires in June 2024. The strategic plan aligns OPTN resources with specific, significant opportunities within the transplant community.

The OPTN strategic planning process can be broken down into three major tasks: brainstorming, focusing and refining, and validating and finalizing. The timeline for this strategic plan has followed the following timeline:

- June 2023 – Brainstorming strategic plan goals with Board and OPTN Committee Chairs
- August-September 2023 – Community feedback and discussion of strategic plan ideas in public comment and regional meetings
- July-November 2023 – Executive Committee drafts a strategic plan and metrics
- December 2024 - Executive Committee refines plan for public comment
- January-March 2024 – Public Comment on draft plan
- March 2024 – Executive Committee reviews public comment feedback
- June 2024 – OPTN Board of Directors takes action on plan
    - After this point, the strategic plan becomes active

The strategic plan is structured as follows: introduction, with context and background; vision, with alignment and continued commitment; goals, including broad and ambitious high-level outcomes; objectives, with direction and focus to achieve goals; and metrics, with actionable insights.

This strategic plan is not an exhaustive list of the OPTN's work, but rather serves as a high-level framework to guide the OPTN's strategic focus. This plan contains goals, objectives, and metrics, but does not detail each needed initiative or project. Engagement with OPTN members, committees, task force(s), and professional societies within the community will shape the formation and implementation

of specific initiatives and a collaborative effort to achieve the outlined goals of this plan. The Executive Committee intentionally selected goals with greater specificity to allow for focus of resources on key opportunities, driving action to ultimately benefit patients.

While building trust through action on opportunities most impactful to the transplant community, the OPTN remains dedicated to our vision. The OPTN promotes long, healthy, and productive lives for persons with organ failure by promoting maximized organ supply, effective and safe care, and equitable organ allocation and access to transplantation; and doing so by balancing competing goals in ways that are transparent, inclusive, and enhance public trust in the national organ donation system.

The OPTN commits our resources to achieve the goals outlined in our Strategic Plan while continuing our dedication to:

- Increase the number of successful transplants.
- Honor the selfless gift of life given by organ donors.
- Safeguard the well-being of patients and living donors.
- Continuously improve the outcomes of patients on the waiting list, living donors, and transplant recipients

The proposed strategic plan 2024-2027 includes the following proposed goals:

- Improve offer acceptance rate: increase opportunities for transplants for patients in need by enhancing offer acceptance
- Optimize organ use: maximize the use of organs for transplantation for waitlisted patients, while maintaining or improving upon past equity gains
- Enhance OPTN efficiency: increase the efficiency of the OPTN through improvement and innovation to serve the greatest number of patients

The Executive Committee considered alternative goals, including goals from the 2021-2024 Strategic Plan. The “Increase the number of transplants” goal aligned with a theme from the June 2023 brainstorming session. The Executive Committee and the community prioritized this theme, while also providing feedback to refine the theme and make the scope more focused. The Executive Committee noted that increasing the number of transplants is a result of the achievement of the vision of the OPTN more than a specific goal.

Past equity gains have been incorporated into the proposed plan’s strategic goal recognizing that as advances in efficiency occur, equity must be maintained or improved.

The Executive Committee also has expressed a desire to increase the number of donors, including both living donors and eligible deceased donors. To this end, the Living Donor Committee has been charged with generating specific tactics to enhance living donation. The Executive Committee recognizes an opportunity for the Board to identify initiatives related to increasing donors in support of the OPTN’s vision

The Executive Committee recognized that all goals focus on benefiting patients, and intentionally wrote each goal to emphasize its impact on patients. The Executive Committee also added an introduction that focuses on patients and donors.

Goal 1: Improve Offer Acceptance Rate: Increase Opportunities for Transplants by Enhancing Offer Acceptance

- Objective 1: Develop, implement, and effectively promote educational programs for patients and transplant programs focused on understanding offer acceptance

- Objective 2: Collaborate with stakeholders to improve offer and acceptance processes to increase consistency
- Metrics: Increased offer acceptance rates (overall), percentage of completed educational offerings (objective 1), percentage of programs utilizing educational offerings (objective 1), decreased time from first offer to offer acceptance (objective 2), decreased variation in time from first offer to offer acceptance (objective 2), and decreased number of offer declines (objective 2)

Goal 2: Optimize Organ Use: Maximize the use of organs for transplantation for waitlisted patients, while maintain or improving upon past equity gains

- Objective 1: Collaborate with stakeholders to identify and reduce key barriers influencing organ non-use.
- Objective 2: Disseminate and promote best practices and effective strategies for reducing organ non-use across the transplantation community.
- Objective 3: Explore and evaluate alternative allocation strategies for organs at high risk of non-use.
- Metrics: decreased % of organs recovered for transplant and not transplanted (kidney and liver) (Overall), decreased % of organs not recovered for transplant from deceased organ donors (heart and lung) (Overall), maintaining or Improving Equity: Access-to-Transplant Scores (ATS) (Overall), achievement of milestones in identifying and addressing key barriers to organ non-use. (Objective 1), decreased variation of risk adjusted non-use rate by OPOs (Objective 2), and decreased High risk organ non-use rate (Objective 3)

Goal 3: Enhance OPTN Efficiency: Increase the efficiency of the OPTN through improvement and innovation

- Objective 1: Refine the policy development and implementation process to be more efficient and strategically aligned.
- Objective 2: Enhance OPTN data collection: increasing availability of actionable data while reducing member burden.
- Metrics: decreased policy development time (Objective 1), decreased policy implementation time (Objective 1), policy alignment with the strategic plan (Objective 1), stakeholder satisfaction in the policy development process (Objective 1), and milestone achievement in data optimization (Objective 2)

Recognizing the need to prioritize and manage work differently, a Board of Directors workgroup will be launched in early 2024 to refine the project prioritization and approval processes. This plan will be managed by the Board and Executive Committee through regular reviews of strategic plan metric results, review of OPTN resource allocation, and discussion of community needs. This plan is intentionally structured to provide flexibility and latitude to the Board to be responsive to the needs of the community. Specific initiatives or projects are not included in the plan, but rather will be selected and approved by the Board or Executive Committee.

Questions for Consideration:

- Do you agree with the Board's proposed areas of strategic focus for the 2024-2027 plan?
- Is a goal or objective missing from this plan that should be considered a strategic priority?
- Are there goals or objectives that should not be included in this plan? If so, should they be maintained in the OPTN's future operations or discontinued altogether?

- Are the stated performance metrics sufficient, measurable, and specific? Are metrics missing from this plan that are needed to provide a holistic view of progress on strategic priorities?
- What organs are at the greatest risk of non-use?
    - What characteristics or criteria describe those organs?

Current Kidney Committee Projects and alignment with current strategic plan goals:

Project Title	Project Status	Primary Strategic Plan Goal
Continuous Distribution of Kidneys • Update Dual Kidney • Update Kidney Minimum Acceptance Criteria and Remove National Kidney Requirements • Establish Kidney Review Boards • Update Kidney Medical Urgency Definition • Carry-Over Refusals in Released Organs • Update KDPI for En Bloc Allocation	Evidence Gathering	**Increase equity in access to transplants** Increase the number of transplants **Improve waitlist patient, living donor, and transplant recipient outcomes**
Align OPTN KPDPP Blood Type Matching Policy Alignments and Establish Donor Re-Evaluation Requirements	Approved but not yet implemented	Increase the number of transplants

Summary of discussion:

Committee members sought feedback on how continuous distribution (CD) will fit into the strategic plan. The Chair pointed out that, though much work has gone into developing continuous distribution allocation frameworks across organ specific committees, there is no reference to this work and the required resources in the plan as drafted. A committee member noted that, though efficiency is a major focus on the new strategic plan, it is only one element of the continuous distribution framework. The Chair asked if the Executive Committee and OPTN Board of Directors expect continuous distribution to remain a priority for the Kidney Committee, as this will be critical in defining the Committee's work going forward.

Highlighting the OPTN's alignment with stated goals and recommendations in the National Academies of Sciences, Engineering, and Medicine (NASEM) report[1], the Executive Committee representative assured Committee members that work on advancing continuous distribution should continue, as it will help to advance these recommendations towards a more equitable, efficient transplantation system. The Executive Committee Representative noted that the development of new allocation frameworks presents an opportunity to identify and implement ways to improve system efficiency, transplant more organs, and reduce non-use of organs.

[1] Realizing the Promise of Equity in the Organ Transplant System (2022) https://nap.nationalacademies.org/read/26364/chapter/1 (Accessed on March 19, 2024)

A Committee member noted that it will be important to define what "successful transplant" means, as the answer here will be variable depending on both candidate and donor circumstances and considerations, including clinical needs and transplant goals.

Concern was raised by a Committee member regarding equity being given less priority in the new strategic plan than it has in the past. The member voiced concerns that a hyperfocus on data and efficiency may reflect satisfaction with the current level of equity in the system and noted that there are still key areas for improvement in equity. The member highlighted the importance of equity for rural, Hispanic, and non-English speaking patients, and for subsets of patients that there may not be significant data on. The Executive Committee representative noted that the Expeditious Task Force is looking at equity as part of its focus and confirmed that equity remains a key focus for the OPTN. The Executive Committee representative shared that the Task Force is creating a dashboard that will include equity and remarked that this feedback will be shared with the Executive Committee.

A Committee member asked how this new strategic plan and its objectives and initiatives will be conveyed to the general public and the patient community to reinforce that the current state of organ transplantation is going to be improved and more patient-centered/patient-focused. The Executive Committee representative shared that she was unable to provide a specific answer but noted that transparency is more meaningful than ever, and that the OPTN is prioritizing improved and increased communication with patients. The Executive Committee representative also remarked that patient and donor family representatives on Committees play an important role in communicating patient community needs and expectations.

2. Defining Hard to Place: Clinical Definition

The Committee continued discussions to develop a definition of "hard to place" deceased donor kidneys.

Presentation Summary:

The objective of this discussion is to develop a preliminary, evidence-based definition for "kidneys at risk of non-use"

- For our purposes, this label is being used interchangeably with "hard to place" kidneys
- Preliminary – the Committee will be able to modify and tweak this definition as needed, for a variety of purposes that such a definition will be used for
- Evidence based – draw upon your knowledge and discussions of literature and data in consideration of this definition, as well sharing your expertise

A consensus definition will provide a greater standard in defining "hard to place" and kidneys "at (increased) risk of non-use"

- Previously, support in public comment for standardizing a definition of "hard to place" kidneys
- Helps to identify which kidneys may become hard to place, or else may benefit from or require an expedited allocation pathway
- Implications for dual kidney, expedited placement, transitioning the kidney minimum acceptance criteria screening tool, etc.

In February, the Committee began initial discussions to define "hard to place" and "kidneys at increased risk of non-use," developing two pathways towards a hard to place definition:

- Clinical, characteristics-based definition – aspects that may make an organ acceptable for a smaller pool of patients, with greater potential for limited longevity
- Allocation, logistical definition – based on allocation thresholds such as number of center or candidates declining, logistical barriers, etc.
- Cold ischemic time is a factor in both pathways

    - Recognized the importance of OPO discretion related to geography, population, and logistics

The Committee is interested in combining donor and kidney characteristics along with system metrics to define when a kidney is or might become “hard to place." The Committee was previously presented with the results of a data request summarizing deceased donor kidney characteristics and non-use. To date, the committee has explored a characteristics-based definition, talked about the number of center and candidate declines, and reviewed literature on European and United Kingdom rescue pathways for hard to place organs.

During today’s discussions, the Committee will approve a data request for the allocation-logistics thresholds and continue focused discussions regarding clinical definitions.

Data Request Summary:

Previously, the Committee discussed potential allocation-based indicators of “hard to place”

- Number of candidate or center declines, to inform a definition based on sequence number of allocation or number of centers having declined
- Cold ischemic time consideration – 6 hours, noting importance of OPO discretion with regard to distance and flight availability

This data request will examine center declines of kidneys in order to inform a threshold that may be used to determine when a kidney becomes “hard to place.” There is no universal definition for “center declines,” and as a result, this request will explore 4 possible definitions for a center decline:

1. Range refusals: when a transplant program enters a “no” response simultaneously for multiple candidates on the match run
    a. Note: this response does not need to be for all candidates on the match run and does not always mean that these candidates received the offer yet
2. Center declines for all candidates on the match run
3. Center declines for 50+ percent of candidates on the match run
4. Center declines for 75+ percent of candidates on the match run

This data request will only investigate kidney match runs with a final acceptance in 2023, so these are kidneys that have been placed, but may have been placed later in the match run. If there are multiple matches with a final acceptance, the most recent acceptance for each laterality will be selected. If both kidneys were placed on the same match run, the final acceptance is that for the last kidney placed, where appropriate. When counting the number of candidates for which there was a decline per center decline definitions 1-4, bypassed candidates and candidates screened from offer filters will be excluded.

For each center decline definition, the following will be provided overall and by KDPI:

- Graph 1: Boxplot of distribution of center declines (per definition 1-4)
    - For each match run, calculate the number of center declines per definition and graph the distribution of that metric across all match runs
- Graph 2: Boxplot of the distribution of the percent of centers that had a center decline (per definition 1-4)
    - For each match run, calculate the center decline metric as a percent of all centers that exhibited the center decline behavior and graph that percent across all match runs
- Graph 3: Distribution of the percent of all candidates involved in center decline (per definition 1-4)

Summary of discussion:

The Committee approved the OPTN data request for allocation-logistics thresholds and continued focused discussions regarding clinical definitions for review at a future meeting.

The Chair remarked asked if the range refusal would be per center, or if this would investigate patterns between centers on a match run. Staff responded that they plan to find out how many centers entered a range refusal, and for those centers that entered a range refusal on a single match run, how many candidates did they decline for, and how big of a proportion the declined candidates make up of all their candidates on the match run. Staff continued that this will be aggregated across 2023 match runs to show a distribution of range refusals. Staff explained that, on one match run, it is possible to see many centers utilizing the range refusal as opposed to few. The Chair asked if the refusals can be distinguished pre- and post-cross clamp. Staff remarked that this can be added, and that as drafted, the distribution will also be stratified by KDPI.

One member shared that the OPTN has previously run a study on kidney accelerated placement, and asked how what was learned from that will be incorporated here. Staff shared that this is something the Expedited Placement Subcommittee plans to discuss, noting that this Subcommittee will do an additional literature review to gain understanding of lessons learned from previous and current expedited placement processes, in both kidney and other organ allocation. The member remarked that this is a huge topic that the American Society of Transplant Surgeons talked about expedited placement recently and recommended sending a survey to the transplant community to hear their suggestions. The member continued that community feedback is critical to building an effective expedited placement pathway.

Staff then provided a recap of the Committee's previous discussions regarding "hard to place."

Presentation Summary:

OPTN Contractor staff reminded the Committee regarding its last conversation regarding "hard to place", which included the:

- The importance of patient education to allow for shared decision making in the offer process. Having discussion even before offers to understand acceptable level of risk tolerance is key to changing the allocation pathway.
- Prioritizing simplicity, making any changes comprehensive and understandable for ease of communication to both transplant professionals and candidates and their caregivers.
- The importance of OPO discretion, acknowledging that national policy should account for variation in geography, populations, population needs, logistics and other elements.
- Recognition that not every organ that is recovered may be appropriate and safe for transplantation.
- Graft longevity as part of the decision-making process. This is informed by the organ itself as well as donor and recipient characteristics, recipient care, and graft management over time.

Staff noted that, previously, the Committee had recognized that "hard to place" is informed by combinations of multiple characteristics, with more characteristics leading to increased risk. A high kidney donor risk index (KDRI) score was noted as a general risk factor. The Committee will be asked to explore if there is a KDRI or KDPI threshold to be flagged. Additionally, the Committee had briefly discussed nuanced clinical indicators such as proteinuria or anuria. Can additional context for this be drawn from biopsy results and kidney pump numbers- and will this benefit from directly referencing this data as opposed to clinical characteristics that could potentially be indicative of concerning biopsy or

pumping results? Contractor Staff asked Committee members to share their thoughts on whether pulling out clinical indicators that may create concern post- cross-clamp are more valuable than the biopsy and pump data alone.

Summary of Discussion:

Staff asked the Committee if it makes sense for the definition to include clinical characteristics that can indicate potentially concern results post-cross clamp, or if it is preferable to rely instead on those results. The Chair remarked that it may be okay to include the initial clinical indicators and compare these indicators as more data becomes available to compare. Staff noted that there may not be data on proteinuria and anuria, particularly as data collection for these items is inconsistent. Another member agreed, noting that proteinuria is particularly nuanced in its reliability. The member explained that deceased donor urinalysis is sometimes performed using a dipstick and can falsely indicate evidence of proteinuria that is not clinically relevant. The member explained that because of this, many OPOs don't test deceased donors for proteinuria. The member added that biopsy and pump numbers are helpful, but that information is not available until many hours after cross clamp. The member continued that biopsy and pump numbers may not be as helpful as criteria to trigger expedited placement due to these inherent timing constraints. The member remarked that there are many factors that may indicate an organ is "hard to place" or at risk of non-use, and some of them are more impactful in combination with other factors, making the definition of "hard to place" somewhat of a moving target. The member explained that certain characteristics may make one donor "hard to place" but not another due to other clinical, anatomical, or even geographical and timing factors. The member concluded that the best variable that summarizes all of these characteristics and how they contribute to an organ being "hard to place" is difficulty in placing the organ itself, which could be indicated by a certain number of recipients or centers having declined. The member explained that it becomes obvious there is something concerning with the organs when a match run with several provisional yeses ends up with more than 100 declines, and that at this point, usually the organs have been recovered. The member continued that the definition of "hard to place" difference for each transplant center, each clinician, and each patient, and that it is difficult to have an objective definition.

The Chair agreed, noting that the definition of "hard to place" and "at risk of non-use" will be important to addressing the September OPTN Board resolution. The Chair remarked that simplifying the definition into pre- and post-cross clamp may help, but agreed that most of the time, it will become most evident that an organ is hard to place after recovery. The Chair continued that there are patterns evident in allocation "hard to place" organs, and that it be would helpful to try to identify these patterns, along with key characteristics.

Upcoming Meetings

- April 15, 2024 conference call
- May 20, 2024 conference call
- June 17, 2024 conference call

Attendance

- **Committee Members**
  - Jim Kim
  - Sanjeev Akkina
  - Marian Charlton
  - Patrick Gee
  - Caroline Jadlowiec
  - Chandrasekar Santhanakrishnan
  - John Lunz
  - Martha Pavlakis
  - Reza Saidi
  - Eloise Salmon
  - Curtis Warfield
- **HRSA Representatives**
  - James Bowman
- **SRTR Staff**
  - Bryn Thompson
  - Grace Lyden
  - Jonathan Miller
  - Jodi Smith
- **UNOS Staff**
  - Kayla Temple
  - Shandie Covington
  - Kaitlin Swanner
  - Keighly Bradbrook
  - Lauren Motley
  - Thomas Dolan
  - Carly Layman
  - Ben Wolford
- **Other**
  - Ginny McBride (Executive Committee)