

**OPTN Patient Affairs Committee
Meeting Summary
February 16, 2024
Houston, Texas**

**Garrett Erdle, MBA, Chair
Molly McCarthy, Vice Chair**

Introduction

The OPTN Patient Affairs Committee (The Committee) met in Houston, Texas, on 02/16/2024 to discuss the following agenda items:

1. Welcome and Introductions
2. OPTN President Welcome
3. Public Comment: *OPTN Strategic Plan 2024-2027*
4. Patient Impact: CPRA and Other Topics
5. Task Force Update
6. Pancreas for Research: Impact of CMS Final Rule on OPO Metrics and Procedural Trends in the Procurement of Pancreata for Research
7. Data Report: *Demographics of Inactive Candidates Across Organs*
8. Public Comment: *Refit Kidney Donor Profile Index Without Race and Hepatitis C Virus*
9. Pre-Waitlist Data Update
10. Closing Comments

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

1. Welcome and Introductions

The Chair welcomed the members of the Committee and the guests of the meeting. Each attendee took a moment to introduce themselves.

Summary of discussion:

The Committee did not make any decisions.

2. OPTN President Welcome

The President of the OPTN presented an overview of the state of the OPTN and how the Board of the OPTN is evolving.

Presentation summary:

In February, Health Resources and Services Administration (HRSA) released a draft Request for Proposal (RFP), with the final version anticipated to be released in March. The draft RFP delineates various areas of work, including OPTN Board Support and Operations. Within Operations, four domains are specified: Transformation Services, OPTN Operations, Organ Allocation and Distribution System (Matching), Information Technology, and Data, along with Communications. These outlined areas encompass a broad scope of responsibilities and initiatives aimed at supporting the operations and functions of the OPTN.

The Expeditious Task Force is made up of a group of donation and transplant community members who are committed to increasing the number of successful deceased donor transplants and improving the efficiency with which organs are allocated. The task force intends to utilize effective quality improvement methods to quickly test potential improvements, utilize effective collaborative improvement methodologies to spread effective practices and drive improvement, and engage with the community in new ways to solicit feedback, encourage participation, and share findings. The task force's bold aim is to achieve 60,000 transplants by the year 2026.

The presenter also highlighted how offer filters have improved organ allocation efficiency. The offer filters reduce the offers that a center may get by about 45%, which helps get the organ to the right person in a much quicker manner. In addition, to improve access to the transplant OPTN Waiting List, the OPTN has been focused on structuring data processes that improve pre-waitlist data collection.

Summary of discussion:

The Committee did not make any decisions.

The Vice Chair expressed intrigue regarding the 60,000-transplant goal and inquired about the underlying information and methodology used to arrive at this figure, expressing interest in sharing such insights with the committee. She emphasized the importance of understanding the dependencies and risks associated with this goal, highlighting opportunities for the committee to contribute and support. In response, the President of the OPTN commended the suggestion, acknowledging its value. She assured the committee that efforts would be made to compile and disseminate the necessary details, enabling informed discussion and strategic engagement moving forward.

A member raised concerns about the potential ramifications of expanding mileage on the increased occurrence of allocation out of sequence. In response, the presenter assured the committee that this aspect had indeed been examined, highlighting ongoing efforts by the utilization workgroup of the task force to gather retrospective data on the matter. Additionally, she mentioned plans for a prospective qualitative study, where a selection of allocation out of sequence cases would be subject to in-depth qualitative research. This approach aims to provide deeper insights into the underlying reasons behind such occurrences, enhancing understanding and informing potential solutions.

A member expressed her curiosity regarding the capacity of transplant centers, highlighting the importance of understanding their ability to project the number of transplants they can perform annually. She emphasized concerns about capacity and inquired about the OPTN's plans to address this issue. In response, the OPTN President outlined a strategy involving a group of leaders from Organ Procurement Organizations (OPOs) and the transplant community who will conduct seminars in various regions. These seminars aim to engage C-suite personnel from transplant centers, drawing on successful individuals within the region to provide training and mentorship. The President noted that while many transplant centers possess the capacity for increased activity, they may face obstacles preventing them from realizing their full potential. Addressing these challenges is a key objective of the seminars, aiming to support centers in maximizing their capacity and contribution to the transplantation field.

3. Public Comment: *OPTN Strategic Plan 2024-2027*

A member of the OPTN Board of Directors presented the public comment proposal *OPTN Strategic Plan 2024-2027* to the Committee.

Presentation summary:

The OPTN Board of Directors adopts a new strategic plan every 3 years to align resources with significant opportunities. The current plan expires June 2024, and a new one will go into effect July 2024. The strategic plan creates a high-level framework to guide OPTN priorities and focus over the next 3 years. It contains goals, objectives and metrics but does not detail every initiative or project since flexibility is needed over time. The vision is to promote long, healthy, and productive lives for people with organ failure by promoting maximized organ supply, ensuring effective and safe care, and equitable allocation, while balancing competing goals transparently. The OPTN is committed to achieving the goals outlined in the Strategic Plan while continuing a 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, and continuously improve the outcomes of patients on the waiting list, living donors, and transplant recipients.

The Strategic Plan goals are:

- 1) Improve organ offer acceptance rates
- 2) Optimize organ use
- 3) Enhance OPTN efficiency.

The first goal, improve offer acceptance rate, seeks to increase opportunities for transplants by enhancing offer acceptance. The first objective for the goal is to develop, implement, and effectively promote education programs for patients and transplant programs focused on understanding offer acceptance. The second objective seeks to collaborate with stakeholders to improve offer and acceptance processes to increase consistency. The metrics for this goal include increase in offer acceptance rates overall, percentage of completed learnings, percentage of programs utilizing education offerings, decreased time from first offer to offer acceptance, decreased variation in time from first offer to offer acceptance, and decreased number of offer declines.

The second goal, optimize organ use, seeks to maximize the use of organs for transplantation for waitlisted patients, while maintaining or improving upon past equity gains. The first objective of this goal is to collaborate with stakeholders to identify and reduce key barriers influencing organ non-use. The second objective is to disseminate and promote best practices and effective strategies for reducing organ non-use across the transplantation community. The third objective is to explore and evaluate alternative allocation strategies for organs at high risk of non-use. The metric for this goal includes an overall decrease in the percentage of organs recovered and not transplanted, an overall decrease in percentage of organs not recovered for transplant from deceased organ donors, maintaining or improving equity, achievement of milestones in identifying and addressing key barriers to organ non-use, decreased variation of risk adjust non-use rate by organ procurement organizations (OPOs), and decreased high risk organ non-use rate.

The third goal in the proposal is to enhance OPTN efficiency through improvement and innovation. The first objective of this goal is to refine the policy development and implementation process to be more efficient and strategically aligned. The second objective is to enhance OPTN data collection, increasing the availability of actionable data while reducing member burden. The metrics for this goal include a decrease in policy development time, a decrease in policy implementation time, policy alignment with the strategic plan, stakeholder satisfaction in the policy development process, and milestone achievement in data optimization.

Past equity gains have been incorporated into the proposed plan's strategic goals recognizing that as advances in efficiency occur, equity must be maintained or improved. The desire is to increase donors,

both living and eligible. The Living Donor Committee has been charged with generating specific tactics to enhance living donation.

Summary of discussion:

The Committee chose to submit a public comment on this item.

The Committee discussed the proposal and provided the following commentary which was entered into the official public comment:

The OPTN Patient Affairs Committee agrees that the overall goals of the strategic plan are aligned with the mission and vision of the OPTN but is concerned that the plan is far too vague and lacks specificity. The metrics need to be numeric and more information should be provided on how such metrics will be developed, monitored and tracked, with aspirational goals and related timelines of achievement. The metrics need to consider the current state and should be more granular so the OPTN can track if it is on target to achieve the goals within the 3-year time period, or if the OPTN needs to change course or readjust the plan if it is not on track to meet the goals. The Committee strongly recommends considering how living donation fits into the goal to increase opportunities for transplants, and that living donation should be an additive part of the plan. The Committee also recommends targeting a specific percentage decrease in the number of patients on the waiting list with a milestone date. Metrics concerning graft and patient survival across 1 year, 5 years, 10 years and beyond should be included in the strategic plan. The Committee would also like to see specific initiatives to increase transplants included in the plan, as well as initiatives to increase awareness, education, and patient engagement regarding the organ transplant process with all communities, but especially those who are underserved. The education of candidates on the risks and benefits of certain organs is directly tied to increasing organ offer acceptance rates. This empowers candidates to make the best decision for themselves. The Committee is also concerned by the lack of specificity regarding equity in transplant. The Committee also noted that this plan, and the goals within it, could be altered at the conclusion of the current OPTN contract; this should be identified in the plan as a significant risk factor.

4. Patient Impact: CPRA and Other Topics

The Vice Chair of the OPTN Histocompatibility Committee and a representative from the Scientific Registry of Transplant Recipients (SRTR) presented on technical errors that were made in the previous year.

Presentation summary:

The OPTN Histocompatibility Committee Vice Chair provided background and the calculation used for the Calculated Panel Reactive Antibody (CPRA) score, which measures a patient's degree of sensitization and estimates the percentage of donors they would be incompatible with. An issue was discovered with a subcontractor's data provided for certain antigens, which led to inaccurate estimations of some patients' CPRA scores between January-December 2022. This potentially impacted allocation priority for some highly sensitized patients. The issue was resolved within a few weeks, and the scores have been corrected.

A representative from the SRTR gave a brief presentation regarding an issue that occurred with modeling blood types in lung continuous distribution. The modeling showed there would be an increase in transplants for patients with blood type O, yet the first monitoring report showed a decrease. There was a miscalculation in the modeling regarding incompatible donors for blood type O recipients. Upon

discovering the error, steps were taken to correct the issue and processes put in place to ensure the same error would not be made in the future.

Summary of discussion:

The Committee did not make any decisions.

The Committee discussed how issues like these, which directly impact patients, should be communicated to patients, and how the thoughts of the Committee should be communicated to the OPTN Board of Directors. One member suggested developing clear communication requirements when patients are impacted by errors. Suggestions were made to develop standardized patient communication requirements for when issues arise, and to allocate resources for robust data analysis to prevent future errors.

An SRTR representative explained the safeguards in place for lung allocation, such as the risk of waitlist mortality formula, an exceptions process, and careful monitoring. They highlighted that organs generally went to the sickest patients despite the error.

Another SRTR representative acknowledged the error and expressed regret. They outlined steps taken to prevent future issues, including new simulation models explicitly designed for continuous allocation and collaboration with external groups. However, he could not guarantee perfection given the complexity involved.

A member expressed appreciation for the self-identification of the issues and swift implementation of the solutions, while stressing that the process should be carefully recorded to prevent repeating mistakes. The member continued, beyond fixing these specific issues, there should be lessons learned across the organization about rigorously checking work, especially when it impacts patients' lives.

Another member emphasized finding the right balance between thorough testing and timely implementation, recommending a robust process review.

Multiple members highlighted the importance of patient engagement, robust safeguards, transparent communication, and continuous improvement in organ allocation policies and processes to minimize negative impacts on patients.

5. Task Force Update

The Committee was provided with an update regarding the Expeditious Task Force's progress.

Presentation summary:

Background:

- The pillars of the task force include growth, efficiency, and use and utilization. These pillars are through the lens of promoting equity and safety for patients.
- Initial expeditious initiatives include designing rescue pathway variance protocols, designing studies to better understand non-use and non-utilization, evaluating OPTN bylaws/policies that may be barriers to utilization and efficiency, hosting a community event to address challenges in utilization and efficiency, and securing commitments for growth and support for initiatives.

Community Forum Planning:

- This is a suggestion made by the Expeditious Task Force that would consider separate, patient-focused events, hospital C-suite targeted sessions on growth and financials, aligning

metrics/incentives with payors, and disseminating effective practices and standardizing donor and allocation processes.

Summary of discussion:

The Committee did not make any decisions.

During the discussion, a member highlighted the common issue of pre-transplant patients' lack of understanding about the OPTN and the transplant system. She emphasized the importance of providing comprehensive education upfront to alleviate confusion, particularly among those who are waitlisted. In response, the presenter acknowledged the need to address this issue and suggested standardization across transplant centers to ensure consistent and thorough patient education, enabling them to navigate the transplant process confidently.

The presenter underscored the significance of having a well-educated population on the transplant waitlist, emphasizing the importance of maintaining a connection with their changing risk tolerance as they progress over time. Building on this point, a member stressed the importance of patients communicating their risk tolerance to healthcare providers, highlighting the discrepancy between a patient's risk tolerance and that of the transplant center. By establishing standardized procedures and encouraging open communication between patients and transplant centers, the member emphasized the potential to improve the quality of care and patient outcomes within the transplant community.

A member proposed prioritizing sufficient time for patient interactions during discussions with C-suite personnel about patient education. They stressed the importance of ensuring patients fully understand their condition and treatment process, particularly for those coping with physiological changes like memory loss. The presenter recognized the value of this suggestion and committed to integrating it into future discussions with C-suite executives and medical professionals.

A member brought attention to an ongoing initiative involving an organization piloting a grant for a shared decision aid aimed at assisting with organ offers. They suggested that this endeavor could serve as a valuable resource for the task force, potentially eliminating the need to duplicate efforts by reinventing solutions already in development.

A member proposed developing a patient-tailored interface to enhance education and information dissemination. They suggested this interface could allow patients to input data, aiding their understanding of key aspects like waiting times and transplant likelihood. For example, patients could estimate the wait time for a kidney with a desired Kidney Donor Profile Index (KDPI). The presenter enthusiastically supported this idea, recognizing its potential to align patient and transplant center risk tolerance. They highlighted its significance in enhancing patient education and decision-making. Another member agreed, emphasizing the potential of such an interface to bolster education and information components.

6. Pancreas for Research: Impact of CMS Final Rule on OPO Metrics and Procedural Trends in the Procurement of Pancreata for Research

Representatives from SRTR gave a presentation about pancreata procured for research.

Presentation summary:

The Centers for Medicare and Medicaid Services (CMS) includes pancreases procured and sent for research as part of their metrics for evaluating and recertifying organ procurement organizations (OPOs). CMS cited the Public Health Service Act which states that procured pancreases used for islet cell transplantation or research should be counted for OPO certification/recertification. After CMS published the final rule in December 2019 including research pancreases in the metrics, there was a sharp increase

in OPOs reporting pancreases procured for research. Some OPOs were reclassified into different certification tiers when research pancreases were removed from the metrics calculation.

In January 2023, CMS clarified that "research pancreases" specifically refers to those sent for islet cell research, and OPOs must maintain documentation on the disposition of these pancreases. SRTR analysis shows the increase in reported research pancreases since the original CMS rule, and that it does affect some OPOs' certification tiers, especially those with a large number of reported research pancreases.

Summary of discussion:

The Committee did not make any decisions.

A member expressed concern about the increasing trend of OPOs sending more pancreata for research purposes rather than transplantation. An SRTR representative acknowledged seeing this trend but did not have evidence of OPOs preferentially sending viable pancreata to research over transplant. Another Committee member expressed concern that this practice could artificially manipulate OPO performance metrics tied to their tier ratings, even if no patient was directly impacted since the pancreas demand is low.

Members expressed concern about what actually qualifies as legitimate "research" for the pancreata. A member asked if it had to be an FDA-mandated study, an SRTR representative clarified this is likely true on CMS guidance. The latest CMS clarification in January stipulated that OPOs must maintain documentation showing it went to islet cell research specifically, but the OPTN data system does not capture that granular detail.

Multiple members questioned why there cannot be more stringent requirements for OPOs to validate and report exactly where these research pancreata are going if it is being used as a performance metric.

Another member voiced concern about the surprising spike in pancreata for research occurring despite declining clinical pancreas transplant, and islet cell transplant demand due to medical advancements in diabetes treatment.

One member raised ethical concerns about properly honoring donor family consent and wishes if pancreata were preferentially sent to research over transplant candidacy.

Potential solutions discussed by the Committee included separating out research pancreas metrics entirely from other OPO evaluations, enhancing data collection requirements, or validating that match runs were performed before sending viable pancreata to research over the waitlist. However, the sensitivity of pancreas quality also makes this complex.

7. Data Report: *Demographics of Inactive Candidates Across Organs*

OPTN contractor staff provided an overview of the results from a data report that focused on inactive status.

Presentation summary:

Key Points:

- Kidney registrations, which make up the majority of the waiting list, were more likely to be inactive at snapshot, have a higher median days in inactive status and a longer time on the waiting list before inactivity.
- As educational attainment increased, the count and percent inactive at snapshot, median number of days in an inactive status per year, and number of status changes decreased.

- White, non-Hispanic had the lowest median number of days in an inactive status per year, the lowest days waiting at an active status before first inactivation but were in the middle when it came to the number of status changes per year waiting and percent inactive at snapshot.

Summary of discussion:

The Committee did not make any decisions.

During the discussion, a member found the data on education levels intriguing, noting instances where patients with higher education levels experienced a decrease in median number of days in inactive status. She suggested that these disparities should be areas of focus for the OPTN. Another member countered, stating that education level may not directly relate to waiting list dynamics. Instead, he highlighted a broader societal issue where individuals with higher education are often treated with more respect. They emphasized the need to address this systemic problem, recognizing it as a significant challenge. However, they noted that it might not be inherently tied to the waiting list process itself.

A participant expressed dissatisfaction with the completeness of the data report update, noting previous requests for additional information such as codes attached to definitions for reasons listed as inactive. He also highlighted a desire to capture retired inactive codes and further examine data points lacking identified reasons for inactivity. Expressing interest in initiating another data request, he suggested considering what additional information would be beneficial. The OPTN contractor staff expressed willingness to assist in exploring new avenues for data requests and determining feasibility with available data, noting that the initial request may not have been fulfilled due to insufficient or irrelevant data. Members agreed that obtaining adequate data is crucial for addressing the issue effectively, emphasizing the importance of having sufficient information to form hypotheses and draw conclusions regarding inactive listings.

Amidst discussions regarding vague inactive reason codes, OPTN contractor staff emphasized the importance of establishing clear definitions for data consistency. They suggested that clarifying these definitions could be a collaborative project for the PAC to undertake in partnership with the Data Advisory Committee.

During the discussion, a participant recommended conducting a normality test on the data to assess its distribution and determine if it adheres to a normal distribution. Additionally, they proposed evaluating the process capability to ascertain the organization's ability to meet predefined standards or benchmarks. By performing these tests, he suggested establishing a baseline and identifying areas where improvements may be necessary to meet desired outcomes effectively.

8. Public Comment: *Refit Kidney Donor Profile Index Without Race and Hepatitis C Virus*

The Chair of the OPTN Minority Affairs Committee presented the public comment proposal *Refit Kidney Donor Profile Index Without Race and Hepatitis C Virus* to the Committee.

Presentation summary:

The purpose of the proposal is to remove race and hepatitis C virus from the Kidney Donor Profile Index (KDPI) calculation. The KDPI combines deceased donor factors, including clinical parameters and demographics, to estimate the relative risk of kidney graft failure. It is mapped to a percentile score from 0-100%. The rationale for removing race is that it is a social construct lacking biological meaning, and using it falsely implies African American/Black donor kidneys are of lower quality. Removing race shifts how risk is attributed to clinical factors.

Hepatitis C virus is proposed to be removed because direct-acting antivirals can now effectively cure hepatitis C, and hepatitis C positive donor kidneys show excellent function when transplanted into hepatitis C negative recipients.

While no member actions are required, transplant programs need to be familiar with changes to the KDPI calculator. The number of donors in each KDPI sequence will remain roughly constant, but some donors may change categories impacting candidate matching.

Summary of discussion:

The Committee did not make any decisions.

The Committee discussed the proposal and provided the following commentary which was entered into the official public comment:

The OPTN Patient Affairs Committee fully supports this proposal and would like to thank the OPTN Minority Affairs Committee for their work. Additionally, the PAC thanks MAC for including PAC members in the workgroup while developing this proposal. PAC supports reconsidering inclusion of the APOL1 gene in KDPI once more data is available. PAC members believe that policies that create a disadvantage for people of color should be assessed and updated asap, as any policy or practice that disadvantages any group should be fast tracked for review as a matter of principle, fairness and equity. Many PAC members believe this policy change may lead to lower non-use rates, increased donation within minority communities, and increased transplant rates, and impact should be measured and monitored carefully going forward. Upon implementation, standardized education for patients regarding HCV organs will be needed, particularly since transplant programs currently are not consistent in the education provided to patients. These educational offerings should include traditional written handouts, as well as educational training videos and should be provided in several languages. These educational offerings should be made available to patients early in the process, perhaps even during dialysis, so they may fully understand any potential risks and benefits of accepting these organs. Following implementation, PAC requests review of the monitoring reports when they become available.

9. Pre-Waitlist Data Update

OPTN contractor staff and the OPTN Data Advisory Committee Vice Chair provided the Committee with an overview of the pre-waitlist data project that the DAC is working on.

Presentation summary:

On November 13, 2023, the OPTN Contracting Officer's Representative (COR) from HRSA attended the DAC meeting and requested the following:

- Feedback on the drafted ventilated referral notification data collection
- Feedback on the drafted referral evaluation registration data collection
- OPTN COR shared DAC's feedback will be considered when:
 - Finalizing the HHS Secretarial Directive – coming in early 2024
 - HRSA intends to include the new data collection forms in the 2023 OPTN Data System package.
- Feedback is due to HRSA on January 31, 2024

Impact of Data Collection Changes on Patients:

- Pre-waitlist data will:
 - Provide insight into who gets referred and by whom, who gets evaluated, and who gets approved to be placed on the OPTN Waiting List.

- Facilitate the OPTN’s ability to address disparities in care processes, improve access to organ transplantation, and assess overall system performance.
- Ventilated patient data will:
 - Provide a more objective source of information on procurement practices, management of donor patients, and how these practices affect the supply of deceased donor organs available for transplant.
 - Improve monitoring of OPO performance, and may facilitate quality assurance and performance improvement efforts to reduce the variation of OPO management and support provided to ventilated patients, donors, and donor families.

Summary of discussion:

The Committee did not make any decisions.

During the discussion, a member emphasized the importance of tracking specific data points that the committee has been advocating for, such as home addresses and email addresses, to better inform decision-making processes. However, a participant raised concerns about the use of such data, highlighting the need to carefully consider privacy and appropriate usage, especially since the OPTN does not directly contact patients. Another participant reiterated the challenges of drawing conclusions from inadequate data collection, underscoring the significance of the Data Advisory Committee's efforts in creating a comprehensive data collection form. They stressed the importance of PAC advocating for the inclusion of relevant elements in the form, especially as it undergoes the Office of Management and Budget (OMB) process.

10. Closing Comments

The Chair thanked the Committee and participants for their work and adjourned the meeting.

Upcoming Meeting

- March 19, 2024, virtual

Attendance

- **Committee Members**
 - Garrett Erdle
 - Molly McCarthy
 - Lorrinda Gray-Davis
 - Justin Wilkerson
 - Calvin Henry
 - Jenny Templeton
 - John Sperzel
 - Julie Spear
 - Tonya Gomez
 - Andreas Price
 - Steve Weitzen
 - Kristen Ramsay
 - Sejal Patel
- **HRSA Representatives**
 - Marilyn Levi
 - Mesmin Germain
 - Kala Rochelle
- **SRTR Staff**
 - Allyson Hart
 - Jon Synder
 - Jon Miller
 - Katie Audette
 - Maryam Valapour
 - Nick Wood
- **UNOS Staff**
 - Alex Carmack
 - Kaitlin Swanner
 - Kim Uccellini
 - Desiree Tenenbaum
 - Eric Messick
 - Kelley Poff
 - Courtney Jett
 - Nadine Hoffman
 - Susan Tlusty
 - Roger Brown
 - Jesse Howell
 - Jenna Reformina
 - Kelsi Lindblad
 - Laura Schmitt
 - James Alcorn
- **Other Attendees**
 - Dianne Lapointe Rudow
 - Valinda Jones
 - Jim Sharrock
 - George Surrat

- Jesse Schold
- Gerald Morris
- Alejandro Diez