OPTN Executive Committee Meeting Summary

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Meeting Information: Agenda and Attendees

Thursday, April 3, 2025 | 1:00–2:30 p.m. ET Location of Event: Zoom

Agenda

- Welcome and Announcements
- Policy Oversight Committee (POC) New Project Approvals:
  - Develop Lung Review Board Educational Narrative Examples (Lung Transplantation Committee)
  - 2025 Histocompatibility HLA Table Update (Histocompatibility Committee)
- OPTN Strategic Plan Metrics
- Updates on Current HRSA Directives
  - Allocating Organs Out of Sequence
  - Normothermic Regional Perfusion (NRP)
- Revise Conditions for Access to the OPTN Computer Systems Policy – Next Steps
- Open Discussion
- Adjourn

Attendees

Attendee Name(s)	Affiliation
Emily Blumberg, Richard Formica, Jen Lau, Macey Levan, Lloyd Ratner, Dianne LaPointe Rudow, George Surratt, Andrea Tietjen	OPTN Board of Directors
Aitebureme Aigbe, Stephanie Grosser, Raymond Lynch, Patrick Mauro, Chris McLaughlin	HRSA Representatives
Vanessa Amankwaa, Thomas Barker, George Barnette, Melanie Bartlett, Lori Downing, Jadyn Dunning, Karen Edwards, Emily Elstad, Becca Fritz, Christine Jones, Tessa Kieffer, Anthony LaBarrie, Mary Lavelle, Andrew London, James Montgomery, Laila Odeh, Rachel Shapiro, Christina Sledge, Lee Thompson, Kristen Welker-Hood	OPTN Board Support Staff

Attendee Name(s)	Affiliation
Matt Cafarella, Bryan Carnahan, Jamie Panko, Kelley Poff, Lindsay Larkin, Tynisha Smith	OPTN Operations Contractor Staff
Dennis Lyu: Lung Transplantation Committee (Vice Chair) Gerald Morris: Histocompatibility Committee (Chair) Jennifer Prinz: Policy Oversight Committee (Chair)	OPTN Committee Representatives
Rexanah Wyse Morrissette	OPTN Interim Executive Director

Meeting Summary

Welcome and Announcements

The Executive Committee (EC) meeting began once quorum was established.

New Policy Oversight Committee (POC) New Project Approvals:

The Policy Oversight Committee (POC) chair shared an overview of the policy project process. For each new project, the POC evaluates projects prior to the presentation to the Executive Committee (EC), assesses projects based on standardized questions, and completes a survey that helps determine the project benefit. If the project is approved, the sponsoring committee will develop the full proposal. The EC later reviews and approves the project for public comment. The POC Chair explained the benefit scoring component, and how different benefit score components provide a certain number of points. Lastly, the Chair shared a chart displaying the OPTN Committee Projects with their granular fiscal year estimates by benefit score.

Pediatric Develop Lung Review Board Educational Narrative Examples (Lung Transplantation Committee)

The purpose of this project is to develop 8-10 educational Lung Review Board narrative examples to aid lung transplant programs in improving the consistency and content of narratives submitted to the Lung Review Board (LRB). The LRB recognized an opportunity for more information to be provided in the exception narratives submitted by lung transplant programs. This information could include additional context, data, and/or supporting literature necessary for reviewers to fully understand the history and current condition of patients for which transplant programs are submitting exceptions. This is not a policy proposal and will not go for public comment nor be presented for consideration by the OPTN Board of Directors, but it is being reviewed by the POC and EC as it requires OPTN resources. The POC Chair stated there are very minimal resources to consider for this project as it costs less than $16,000 over two fiscal years. It has a project score of 14 and in the Benefit vs. Cost Plot Quadrant, has a Low Cost, Low Benefit score. The project aligns with the key metric of increased consistency and improved content of lung exception requests that are submitted based on qualitative feedback from Lung Review Board members. The POC discussed: whether this is the right timing for this project in the context of

other work, whether it is sequenced appropriately, if there is additional feedback to improve alignment across projects, and if there are any unintended consequences. The POC had 14 members who recommended that the project move forward to the EC. No members rejected or abstained.

An EC member asked whether there was any discussion of creating a standardized template so these narratives could be used to help standardize the review process across the OPTN. The POC Chair stated that the POC agreed and hopes to use this standardized template to build templates for other organ-specific review boards. One member was concerned about pushing new projects forward without any information about the current budget, and another EC member agreed that the EC needs a total accounting of all expenditures. A member asked the contractor to speak on whether it was financially feasible to do this project. The United Network for Organ Sharing (UNOS) said that this project would fall within the Lung Transplantation Committee which is supported by UNOS staff. The EC Chair stated that the EC should vote and they could circle back to these questions later.

EC voting results: Approve: 7 Reject: 0 Abstain: 1

2025 Histocompatibility HLA Table Update (Histocompatibility Committee)

The purpose of the project is to add necessary p-groups to Table 4-16: Epitope based Unacceptable Antigen Assignment for DPB1, and for these groups to incorporate more precise, multi-field typing. This update will also add C*04:09L to Table 4-7: HLA C Unacceptable Antigen Equivalences, which aligns with the International Immunogenetics (IMGT) information system change of the allele from null to low expression. This will change donor typing, aligning this value with the newest IMGT updates. The resource estimate is $112,274 and is spread across fiscal years 2025-2028. The project score is 91, with a Low Cost, High Benefit score in the Benefit vs. Cost Plot Quadrant. The project aligns with the strategic goal to enhance OPTN efficiency as well as two key metrics: use of p-groups in HLA typing and unacceptable antigen assignment for DPB1, and reporting of C*04:09L in HLA typing. The project is expected to go out for public comment in July 2025. The POC supported the project moving forward on an expedited timeline due to patient safety associated with these types of updates, with 13 voting yes, 1 voting no, and 0 abstaining.

The Chair stated that the patient care aspect is a real concern but not as pressing as it used to be due to tissue typing advances; however, the potential improvements in virtual cross matching would improve system efficiency dramatically. Another member agreed and asked why the project cost is so high. UNOS stated the IT staff goes through an extensive resource-estimating process and this project includes a change to the system, which includes extensive testing and quality checks for changes. The POC Chair said that $40,000 is allocated to the compliance and evaluation piece of the system and $60,000 is allocated to IT management. The Chair of the Histocompatibility Committee said that this work largely stems from building accurate cross talk between the typing table and antibody table.

EC voting results: Approve: 8 Reject: 0

OPTN Strategic Plan Metrics

The OPTN Interim Executive Director provided an update on the OPTN Strategic Plan 2024-2027. She stated that committee members will receive a 19-page report with more details. She provided a high-level overview of the report.

Goal One: Increase Opportunities for Transplants

- Overall acceptance rates have remained relatively stable; however, lung acceptance rates have shown a concerning downward trend since Q1 of 2022. The Director suggested the EC consider how to address this so the OPTN operations contractor can execute needed changes.
- There has been an increase in time from the first to the last electronic offer for most organs except for the liver, which has leveled out, and lung which has begun to decrease since Q3 of 2022. This metric should be watched closely as increasing time between offers can lead to organ viability issues.
- The median number of declines remains relatively stable for heart and liver. Kidney had a small increase after Q1 of 2021 but this has since stabilized. Lung has had additional declines since Q3 of 2022 but this has stabilized recently.
- There has been a steady increase in living donor kidney transplants.
- The Director recommended having policy markers that can be added to graphs to add context. There were about 5-7 policies implemented between 2021-2023 to which some of the declines can be attributed.

Goal Two: Optimize Organ Use

- Heart and lung non-utilization rates are being monitored closely to identify and address barriers to utilization.
- The higher KDPI kidneys are still being utilized at a lower rate and the OPTN needs to continue to look for ways to utilize these organs. The OPTN contractors and community are working to understand the factors contributing to these variations including liver non-use rates by donor age and DCD status.
- The OPTN is continuing to monitor the effects of the policy changes to Access To Transplant scores (ATS) and is seeing progress with the listed OPTN and equity goals.
- The Minority Affairs Committee is working on removing race from KDPI and talking about whether anything else needs to be changed or removed. The Director suggested the EC consider what work should be done to address these things.

Goal Three: Enhancing OPTN Efficiency

- Progress has been made regarding policy development and information timelines.
- The OPTN is ensuring that policy projects are aligned with the strategic goals and have robust policy project benefit scores.

- Discussions are in place regarding quantifying the risk of not doing a project.
- The Director suggested the EC ideate with the POC regarding the policy development process and potentially vote on changes, and this is a 13-step endeavor where HRSA provides input at 4 key points.

Goal Four: Support OPTN Modernization Initiatives

- The OPTN needs to monitor changes from singular events and needs more information from HRSA to better track progress.
- The EC may want to consider reevaluating the four metrics when additional information about HRSA's Optimization Modernization Initiative becomes available.

Since much of the information was presented verbally with short text summaries on a slide, one member said it would be helpful to have dashboards and visuals for members to be able to see this information to help them digest information. Another member expressed concerns about institutional memory regarding KDPI and suggested removing KDPI as a measure or having high KDPI kidneys be allocated to people who are at the bottom of the waitlist. The member said the construct is being used in a way not originally intended.

Updates on Current HRSA Directives

Allocating Organs Out of Sequence

The Chair said the workplan regarding Allocating Organs Out of Sequence (AOOS) was submitted to HRSA on March 31, 2025.

Subsequently the Chair received a letter from the local PDSA for the local effort to try and improve rescue pathways. The idea is good but we cannot go forward in the current form because we are to use the traditional variance pathway rather than a PDSA pathway. The concept could remain but it would have to be worked into a true variance approach. They are now waiting for a response from HRSA to see whether their plan is accepted or not.

One member said that this variance pathway was directed and approved by the EC in the past. This member asked whether the letter from HRSA requires or disallows the EC and the Board from delegating this work because in the past, the Board could do this work. Now it seems like they can't. The member asked if this letter was revoking the role or permissions of the Board?

The EC Chair clarified that they approved a variance that allowed them to circumvent the variance stated in the Final Rule. If they want to conduct experiments to improve AOOS it must follow the variance pathway as articulated within NOTA. The member said that their legal interpretation was that the work of the workgroups was not believed to be against NOTA or the Final Rule, so it is unclear what is different now. HRSA clarified that the direction from them is to follow the NOTA-compliant variance process moving forward. The member asked if HRSA suggested that the whole process was out of compliance with NOTA.

HRSA said the direction is to follow the NOTA-compliant process in the future. The member said the plan in the letter is a three-year plan versus the plan they are looking at now is a rapid three-month project to test things with promise before they are put into policy. So this is a less efficient way of doing things, and since the original plan was not illegal according to NOTA or the Final Rule, it is unclear why they should move to a slower and inefficient pace without a reason. The member requested that HRSA provide the community with a reason.

Normothermic Regional Perfusion (NRP)

The delivery date for the NRP letter is April 30, 2025. The EC stated that for thoracic and abdominal NRP they need to determine how to assess cognitive function and confirm there is no cerebral flow for people moving forward with Donation after Circulatory Death (DCD) donation. There should also be a standardized definition for when a person is confirmed dead and transitions from a person to a donor. A lot of this falls in the domain of the donor hospital, and most hospitals follow the five-minute rule but some places do not, so standardization is needed. This comes from a reporter's ethical concerns that were brought to light. There are two choices: determine a way to ensure cerebral vessels are vented, or a longer stand down time.

One member suggested differentiating between the thoracic and abdominal NRP because they are different, and it would be a problem to have rules implemented that are not relevant or necessary for a certain NRP. If it becomes more difficult to do abdominal NRP and organs are lost it would be a disservice. HRSA clarified the ethical issue that differentiates thoracic and abdominal NRP is the reanimation of the heart. The practicality that this critical comment is addressing is about maintaining the permanence of death by interruption of the cerebral blood flow. The two things that make abdominal NRP a lower but non-zero risk are that the blood flow is lower and that a lower clamp makes the chance of a collateral pathway less, but in children it is still believed to be significant. HRSA stated that the practicality of doing not just interruption of the blood flow but venting above it for abdominal NRP would be just as practical as doing so for thoracic NRP.

Revise Conditions for access to the OPTN Computer Systems Policy – Next Steps

The Network Operations Oversight Committee (NOOC) put together a comprehensive approach to computer safety and a discussion came up that an unintended consequence of this policy is that it could hinder the utilization of UNet for time-sensitive research to place organs without them going to waste.

There were two potential plans: 1) implement the conditions as they were written but insert an exemption for research, carve out individuals using UNet for time-sensitive research, and give them a grace period of 90 days, or 2) expand the definition of facilitating transplants to include research so they can continue in current fashion. They went with the second recommendation and asked NOOC leadership to develop a definition of time-sensitive versus time-insensitive research and then develop data use agreements for the real-time access of UNET. One challenge they are facing is that they know who accesses UNet but they do not know why, and it is difficult to determine if people are in UNet for research or another purpose. The data security provisions have now been put into place.

Open Discussion

The EC Chair described a letter he received from University of California, San Francisco (UCSF). Pediatrics are a population not currently under IRB approval for the Hope Act and there is a delay in implementing the clinical integration of the HOPE Act. UCSF has a young patient with HIV who is highly sensitized and on a time-limited visa, and UCSF wanted to make every opportunity available to this child to get them transplanted. The Chair stated it is medically appropriate to transplant an HIV organ into this child, but there is no way to make UNet realize that the child can be allocated an HIV-positive organ. This has culminated in a request for individual IRB variance. This will be brought for full discussion at the Board meeting on April 17th. One member asked if they need an Ethics Committee review since the child cannot give consent themselves as part of a protected population, and the EC discussed asking UCSF to run this by their Ethics Committee.

One member asked who is managing the paperwork for the Invest Corporation and asked what the plan is to transition that work once the new leadership comes in. AIR stated that Foley-Hoag and AIR are managing the Invest tax filing and insurance and are currently looking into what that means for the Board transition in July. The Chair asked if there is documentation on subjects the Board has been discussing so there is a clear history of what the current Board has done. AIR said that falls into the knowledge transfer that is taking place and information will be sent to the new Board so they can easily track what has been done and what still needs to be done.

HRSA stated that they have refined their policies to make sure that any whistleblower or confidential reporting complaints come through HRSA at the top rather than going through the contractor to improve transparency and maintain HRSA's role as a regulator. This information will be announced on April 10th to the public with a link for the community. The EC Chair asked if there is going to be a mechanism for channeling complaints to the respective vendors. One member asked how any complaints about HRSA will be adjudicated and HRSA said there will be a process for that as well, and the Interim Executive Director stated that every federal agency has an Inspector General that allows for feedback to any federal service. HRSA stated that the new system will be live on April 10th. Someone asked if that would change the role of the compliance officers on the Board and the Interim Executive Director said no.

Another member asked if the NRP standardized data tool will be made after/through the response process or if it is expected to be done prior. HRSA said they will check on this.

Adjourn

The Chair encouraged all members to be present tomorrow, Friday, April 4th, on the 30-minute OPTN Ad Hoc Board Meeting.

All meeting attendees received a feedback form to complete.