

**OPTN Ethics Committee
Meeting Summary
March 14, 2024
In-Person Meeting**

**Andrew Flescher, PhD, Chair
Sanjay Kulkarni, MD, Vice Chair**

Introduction

The Ethics Committee (“Committee”) met in-person in Houston, TX and via WebEx teleconference on 3/14/2024 to discuss the following agenda items:

1. Welcome and Announcements
2. Public Comment Presentation: 2024-2027 OPTN Strategic Plan
3. Public Comment Presentation: Refit Kidney Donor Profile Index (KDPI) without Race and Hepatitis C Virus
4. Allocation out of Sequence and Rescue Pathways White Paper (focus project for OPTN Policy Oversight Committee)
5. Xenotransplantation Memo
6. Public Comment Presentation: Heart Continuous Distribution Update
7. Public Comment Presentation: Clarify Requirements for Pronouncement of Death
8. Timing of Donation Conversations

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

1. Welcome and Announcements

Summary of discussion:

The Chair welcomed members to the call. Members participated in an icebreaker. Staff reminded members that public comment is open until March 19th.

The Expeditious Taskforce held a townhall on March 13th and a recording will be made available. A member, who also serves on the Expeditious Taskforce, gave some updates about discussion and decision-making within the Taskforce. Discussion on Taskforce aims and brainstorming has been occurring across the country at OPTN regional meetings. The member noted some concern that at points, equity is being left out of conversations. Members discussed the identified bold aim of achieving 60,000 transplants by 2025, and how the Taskforce decided on that aim. The Chair thanked the member for serving on the Taskforce and for the update.

2. Public Comment Presentation: 2024-2027 OPTN Strategic Plan

The Committee heard a presentation on the OPTN Executive Committee’s proposal out for public comment, *2024-2027 OPTN Strategic Plan*, and provided feedback.

Presentation Summary:

The OPTN Board of Directors (hereinafter “the Board”) adopts a new strategic plan every three years. The current strategic plan expires in June 2024. The strategic plan aligns OPTN resources with specific, significant opportunities within the transplant community. Recognizing the dynamic nature of the field

of organ donation and transplantation, the OPTN Executive Committee acknowledges the importance of focusing efforts on key areas that hold the potential for substantial impact.

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. The plan's flexibility allows adaptation to emerging opportunities, ensuring responsiveness to the evolving landscape of organ transplantation. 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; a collaborative effort to achieve the outlined goals of this plan. The Executive Committee intentionally selected goals with greater specificity to allow for a focusing of resources on key opportunities, driving action to ultimately benefit patients:

- 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 plan proposes trackable metrics for each of the key goals. The metrics should be impacted by progress towards the strategic plan objectives. One objective or project may impact multiple metrics. Metrics within this plan are intended to be reviewed holistically to assess progress. As projects are developed in detail over the period covered by the strategic plan, appropriate metrics and monitoring plans are maintained for each project. This plan does not define specific resource allocations per goal, but rather provides flexibility. Leveraging insights from regular strategic plan progress reviews, the Board will adjust resources as needed to the greatest benefit of the transplant community.

Summary of discussion:

The Committee provided the following feedback on the proposed strategic plan in the form of an official public comment:

The OPTN Ethics Committee thanks the OPTN Executive Committee for the presentation and for the opportunity to provide feedback on the proposed strategic plan.

The Committee thanks the Executive Committee for including equity in the plan's foundation, however, notes concern that they are not mentioned specifically in the goals, objectives, or metrics. Without being included specifically, the Committee is concerned that important equity concerns will be left out of OPTN work, possibly undermining past gains in this area. The Committee views including equity in the goal as a utility consideration: the OPTN will be its best representative to the transplant community, maintaining the trust of the community, if it is seen as doing its due diligence in featuring all aspects of principles which guide procurement, distribution, and allocation of organ transplantation, including and especially the principle of equity. We fear that if equity is not mentioned specifically in the strategic plan, it will become increasingly under emphasized over time. While the Committee understands the framing chosen to "maintain equity" instead of "improve equity," noting some pressing issues in the system that may require solutions less focused on improving equity, members urge the Executive Committee to consider public trust, transparency, and the importance of not only maintaining, but striving to improve equity in all aspects of the OPTN.

The Committee also notes that it may be helpful to call out more specifically that the goals regarding increased transplants have basis in reducing waitlist mortality, and asks the Executive Committee to consider this in framing the goals, objectives, and metrics. The Committee also sees clear lines between the proposed goals of the strategic plan and current project work, which is promising.

The Committee supports the plan, however, suggests re-working the goals, objectives, and metrics to include both equity and living donation to make it clear to Committees, the transplant community, and the public at large how the “foundations” of the OPTN will continue to be built upon and expanded.

Next steps:

The public comment will be submitted on behalf of the OPTN Ethics Committee.

3. Public Comment Presentation: Refit Kidney Donor Profile Index (KDPI) without Race and Hepatitis C Virus

The Committee heard a presentation on the OPTN Minority Affairs Committee’s proposal out for public comment, *Refit Kidney Donor Profile Index (KDPI) without Race and Hepatitis C Virus*, and provided feedback.

Presentation Summary:

The Kidney Donor Profile Index (KDPI) is a measure that combines deceased donor factors including clinical parameters and demographics to summarize the quality of deceased donor kidneys into a single number. Lower KDPI scores are associated with longer estimated organ function, while higher KDPI scores are associated with shorter estimated organ function and an increased chance of organ non-use. Currently, kidneys from African American/Black and Hepatitis C virus (HCV) positive deceased donors have an increased KDPI of up to 20% for each factor. Race is a poor proxy for human genetic variation and due to innovations in treatment, post-transplant outcomes for HCV positive deceased donor kidney transplants are similar to that of HCV negative donor kidneys. These factors inflate the KDPIs of deceased donor kidneys from African American/Black and HCV positive donors. The OPTN Minority Affairs Committee proposes refitting the KDRI (Kidney Donor Risk Index) and subsequently the KDPI calculation without race or HCV donor factors to better reflect the likelihood of graft failure for kidneys from African American/Black and HCV positive deceased donors.

Summary of Discussion:

The Committee provided the following feedback on the proposal in the form of an official public comment:

The OPTN Ethics Committee thanks the OPTN Minority Affairs Committee for the opportunity to provide feedback on this proposal. The Committee supports this proposal to promote equity. Removing these variables makes sense, as it is now known that the APOL genes confer risk, not race, and that HCV organs are frequently transplanted without incident owing to contemporary treatment. The Committee also notes that KPDI is limited in its predictive ability in general.

Next Steps:

The public comment will be submitted on behalf of the OPTN Ethics Committee.

4. Allocation out of Sequence and Rescue Pathways White Paper (focus project for OPTN Policy Oversight Committee)

The Committee considered revisions to the project focus and scope on Allocation out of Sequence and Rescue Pathways White Paper to finalize submission to OPTN Policy Oversight Committee and OPTN Executive Committee.

Summary of Presentation:

The following information was provided as background for allocation out of sequence from the Vice Chair:

Following the Executive Committee's decision to decline approval of the Living Donor access white paper, in February the Committee discussed other project avenues. Consensus was reached to explore a white paper on ethical analysis of rescue pathways and allocation out of sequence. This was decided given that this is a pressing issue in the OPTN right now, there is support for this idea from OPTN Board of Directors leadership, and it aligns with work of Expeditious Task Force and goals of the OPTN moving forward.

In February, the Committee heard a presentation on allocation out of sequence from New England Donor Services representatives. Key points from this presentation included:

- Expedited placement is consistent with National Organ Transplant Act (NOTA) and the Final Rule
- Process inefficiencies/inefficiencies in allocation system are leading to rising late declines, leading to more allocation out of sequence
- Organ procurement organizations (OPOs) are using varied strategies to allocate out of sequence to place organs at risk of non-use
- Geography plays a role both in allocation out of sequence and in which strategies are used for "organ rescue"

This white paper is currently in the problem analysis stage. In this meeting, the Committee will focus project ideas and scope in preparation for project approval.

Staff also mentioned some lessons learned from past project approvals to improve current methods and messaging.

Summary of Discussion:

A member stated that they appreciated the proposal question asking if allocation out of sequence changes stand in tension with the proposed strategic goals. A member mentioned that the non-use rate of organs is going up along with the rate of allocation out sequence. A member stated that technology allows for organs to travel further than ever before, which may lead to an increase of exceptions, which further may be a cause of increased non-use and allocation out of sequence.

A member said that some data needs to be reevaluated before assumptions are made, such as allocation out of sequence of kidneys and the shift to a 250-mile location radius for allocation. The Chair stated that the first section of the project form should be rewritten with the impacts of policy changes in mind.

Research staff mentioned that in the past, allocation out of sequence data has been aimed more at impact than causal reasons. The Chair said that this should lead to a focus on transparency in the project, and a member agreed that these impacts can also be looked at for ethical research. A member stated that allocation out of sequence increases utility in a variety of ways because it gets more

recipients the organs they need, and he mentioned that project form language should match this, with concurrence from the Committee. The Chair said this should be included in the paper's body, so as not to introduce bias into the research question.

A member stated that there may be pressure to achieve outcome metrics for OPOs, and this should be looked at ethically. The Chair responded that the paper's purpose is to provide ethical analysis, not change policy. The Chair and several members responded that analysis of equity and utility, in various forms, could be included in the project's focus.

Another member was interested in looking into what causes recipients to be passed over for a transplant that was allocated out of sequence, as well as mortality rates in connection with this phenomenon. A member continued that there are inconsistencies with passing over of candidates on a system-level. The Chair pointed out that it cannot be assumed why transplant centers might have taken certain actions out of sequence. A member raised concerns that utility is sometimes considered more than equity. The Chair responded that more organs are being used, while inconsistencies may happen.

When looking at the questions the project aims to address, minor adjustments were made for language with collaboration from the Committee. The Committee decided that the project would focus on kidney, with the understanding that these findings could be applied to other organs. The paper will include a section to address any organ-specific considerations. The Committee also decided that it would be important to add background for the project form readers about the use of match runs in organ transplantation.

Next Steps:

The Committee will continue to discuss the project in April, following when the idea is presented to the Policy Oversight Committee. The Committee will also work to submit a data request.

5. Xenotransplantation Memo

The Committee heard a brief presentation on the Committee's idea to craft a memo to the OPTN Executive Committee and reviewed an initial draft.

Summary of Presentation:

The Chair presented context and background to the purpose of the xenotransplantation memo:

Addressing ethical implications of Xenotransplant was a highly rated idea during the Committee's brainstorming/project idea prioritization. However, the Committee ultimately did not pursue a white paper at that time due to the narrow scope in which the OPTN has permission to address issues concerning xenotransplantation. There are other, important ethical and regulatory issues in xenotransplant that may be pertinent to the OPTN and its work that it is not currently able to address.

A contractor Xenotransplantation Workgroup was formed with the objective of developing a comprehensive list of the questions that will ultimately need to be answered by the time xenotransplantation becomes a common therapy for end stage organ failure. This Workgroup submitted a letter to the OPTN Executive Committee in November 2023¹, which recommended that the "Executive Committee task the OPTN Ethics Committee with an ethical analysis relating to what impacts receipt of a xenograft should have on the allograft waiting list, and how to ethically incorporate xenotransplantation

¹ UNOS Xenotransplantation Workgroup. *Considerations for Xenotransplantation in the United States from the United Network for Organ Sharing*. 2023 Nov 03.

recipients into the OPTN allocation system.” A member prepared a draft memo for Committee consideration today. The Committee then reviewed the letter and provided feedback.

Summary of Discussion:

The Committee considered the questions of time on the deceased donor waitlist and inactive status on the waitlist after xenotransplantation. Members discussed how xenotransplantation affects how a future recipient might receive a deceased donor organ and if this other candidates that may be waiting. The Committee mentioned possible connections to the rule of rescue.

Members also discussed if xenotransplantation recipients should be rewarded in any way for being in a clinical trial. A member asked how clinical trials should be viewed in the paper, and whether those trials be a “bridge” or “destination” for the future of xenotransplantation. Members agreed with this question.

A member discussed the possibilities and concerns of private research on xenotransplant as a new technology entering in the realm of the organ transplantation system, a public good. The Chair responded by saying the Committee can give initial guidance in OPTN relation to xenotransplantation, and that this topic is rapidly evolving. When discussing inclusion of policy guidance, staff responded that the Committee would be unable to give guidance on who would be eligible to get a xenotransplant because of the OPTN’s scope and the scope of the Committee. Members suggested minor language changes regarding the stakeholders section of the memo.

Staff will work with leadership to incorporate edits and finalize the memo.

Next Steps:

The finalized memo will be submitted to the OPTN Executive Committee.

6. Public Comment Presentation: Heart Continuous Distribution Update

The Committee heard a presentation on the OPTN Heart Transplantation Committee’s concept paper out for public comment, *Update on Continuous Distribution of Hearts*, and provided feedback.

Presentation Summary:

In August 2022, the Organ Procurement and Transplantation Network (OPTN) Heart Transplantation Committee initiated an effort to convert the current classification-based heart allocation system to a point-based framework, otherwise known as continuous distribution. The current allocation system groups candidates into classifications based on medical urgency, whether they are adult or pediatric, blood type, and distance between donor and patient hospitals. Waiting time is then used to rank candidates within each classification. Continuous distribution implements a composite allocation score to prioritize candidates. The composite allocation score simultaneously considers candidate and donor attributes. This points-based allocation system will create a more equitable, agile, and transparent allocation system.

This request for feedback document is the next step following the Heart Transplantation Committee’s initial concept paper, which was submitted for public comment during July – September 2023. The request for feedback document is intended to supplement the concept paper by providing information about the Committee’s activities since July 2023. It is also intended to inform the OPTN community about the Values Prioritization Exercise (VPE) available for members of the community to complete during January – March 2024. The VPE is a method of collecting community input regarding how certain aspects of heart allocation should be prioritized against each other. Additionally, the document describes the use of mathematical optimization to refine the Heart Committee’s initial ideas for

attribute rating scales and, as with the initial concept paper, the request for feedback document solicits the community's feedback about the Heart Committee's work to date and outlines the anticipated next steps for the Committee's activities.

Summary of Discussion:

The Committee provided the following feedback on the concept paper in the form of an official public comment:

The OPTN Ethics Committee thanks the OPTN Heart Transplantation for the opportunity to provide continued feedback on the development of continuous distribution. The Committee recognizes the importance of the VPE as a way to gather community input and looks forward to the report-out of the results. Additionally, members appreciated the Heart Committee's thinking regarding not including post-transplant survival as an attribute at this time- it is important to consider how any allocation change may disadvantage high risk candidates. In line with the Ethics Committee's past public comment on the development of heart continuous distribution, members urge the Heart Committee to keep equity concerns with prior living donors in mind. Transparency and public perception will be important to consider as the Heart Committee further discusses the PLD attribute.

Next Steps:

The public comment will be submitted on behalf of the OPTN Ethics Committee.

7. Public Comment Presentation: Clarify Requirements for Pronouncement of Death

The Committee heard a presentation on the OPTN Organ Procurement Organization (OPO) Committee's concept paper out for public comment, *Clarify Requirements for Pronouncement of Death*, and provided feedback.

Presentation Summary:

This proposal would clarify that donor hospital healthcare professionals who declare the death of a potential deceased donor cannot be involved in any aspect of the organ recovery procedure or transplantation of that donor's organs. The number of donation after circulatory death (DCD) donors has been increasing each year as organ procurement organizations (OPOs) focus efforts to increase the number of deceased donor organs available for transplant. OPOs employ or contract with multiple physicians who are donor hospital intensivists to provide on-call medical director services. These physicians may need to participate in the pronouncement of death as part of the donor's hospital healthcare team when not on-call for the OPO. If anyone employed by the OPO in any capacity is prohibited from participating in the pronouncement of death of a DCD donor, it could result in the abandonment of a DCD donor if there are not additional donor hospital staff who can pronounce death.

While there are existing policies that address the restrictions on donor hospital healthcare team members participating in the organ recovery and transplantation of organs if declaring death, there is a need to be consistent between the policies addressing DCD and donation after brain death (DBD). Additionally, avoiding any conflicts of interest during the pronouncement of death is a vital part of maintaining public trust in the donation and organ procurement system. The OPO Committee is requesting public comment feedback, including input on the following questions:

- Are there concerns about these changes impacting patient or donor care?
- Are there any ethical considerations with these changes?
- Does the proposed policy language provide adequate clarity for donor hospital healthcare workers who may also provide on-call support for OPOs?

- Does this proposal help to increase or maintain the public trust in the declaration of death of potential organ donors?

Summary of Discussion:

The Committee provided the following feedback on the proposal in the form of an official public comment:

The OPTN Ethics Committee thanks the OPTN Organ Procurement Organization for their development of this proposal and the opportunity to provide feedback. The Committee supports this proposal, and notes that more clarity regarding the policy changes proposed and their impact may be helpful. Members appreciated the desire to reduce conflicts of interest or the perception of conflicts of interest, as public trust is paramount in donation and transplantation. A member noted that it may be helpful to suggest that OPOs work with donor hospitals to make changes to their internal policies for matters outside of OPTN jurisdiction related to this issue.

Next Steps:

The public comment will be submitted on behalf of the OPTN Ethics Committee.

8. Timing of Donation Conversations

The OPTN OPO Committee Chair joined to present a new project idea centered around the timing of family discussions for donation, and requested Ethics Committee input.

Presentation Summary:

OPTN Policy 2.15: Requirements for Controlled Donation after Circulatory Death (DCD) Protocols states that “Prior to the OPO initiating any discussion with the legal next-of-kin about organ donation for a potential DCD donor, the OPO must confirm that the legal next-of-kin has elected to withdraw life sustaining medical treatment.” The presenter explained that this language can be tricky and can pose a significant limitation on the hospital’s ability to involve the family in a conversation about what the withdrawal of treatment may look like.

This policy was developed in 2012 and became effective in 2014. During development, there was some concern noted from several organizations, including:

- Concerns about approaching conscious ventilator-dependent patients
- Concerns about the ethical safeguard that a donor family not be approached about organ donation
- Concerns about a patient being “evaluated” as a donation after circulatory death (DCD) candidate prior to a decision

In 2012, the Ethics Committee provided the following feedback during proposal development:

- Supported donor evaluation prior to decision to withdraw support
- Supported separation between decision to withdraw care and decision to donate
- Families should “generally be approached” about organ donation after the evaluation and the decision to withdraw support has occurred
- It would not be prudent for OPTN policy to flatly prohibit donation discussion prior to the decision to withdraw support

In 2019, the question re-surfaced through a member question, emails to OPO Committee leadership, and discussions at conferences. There was concern that the DCD discussion was occurring too late, and a request from hospitals that OPOs be a part of the withdrawal decision.

The OPO Committee is interested in possibly modifying this policy, and is considering the following key questions:

- Should OPOs be allowed to initiate donation discussions?
 - Current policy prevents OPOs from “initiating” donation discussions *prior* to the decision to withdraw life-sustaining measures
- When can OPOs provide donation information to the healthcare team and/or donor family?
 - Current policy does not prohibit donation discussions if initiated by the donor family or the healthcare team
- What ethical and/or legal issues need to be considered?
- What organizations should the committee engage with during these upcoming discussions?

The presenter also requested two volunteers to serve on a workgroup for development of this project.

Summary of Discussion:

A member explained that there are many articles that underscored the importance of separating the donation discussion from the decision to withdraw life-sustaining care, however, that these conversations do not always proceed in a best-case scenario. This member continued that in the Committee’s work on Normothermic Regional Perfusion (NRP), there was an argument that NRP is aimed at honoring the donor’s wishes to donate, a decision that has been made in the context of life-sustaining treatment not being an option. This member explained that changing the policy such that the conversation to withdrawal care and proceed with donation concurrently may mean losing some of these aspects involved in respect for persons.

The presenter clarified that the question the OPO Committee is trying to answer is that if a family making the decision around withdrawal needs or should have information about what donation entails at the time of that decision. The presenter explained that often, families do not understand the timeframe involved in donation. The Chair responded that during the Committee’s discussions about NRP, it was so important to find the balance between transparency and appropriate disclosure. The Chair continued that it is important to have a family to have the appropriate information to make a decision about donation at the right time, but not so early that there is any perceived pressure to proceed with donation. The presenter agreed, underscoring that there needs to be separation between the decision to withdraw care and the conversation to approach donation, however, that the family needs appropriate information about what withdrawal of care looks like (provided by the hospital staff) and as part of this, information about donation can be discussed, separately, by OPO staff. This is before the family has formally announced the decision to withdraw care, but after they are aware of the futility of the situation and that decisioning is occurring as part of an end-of-life decision.

The Chair explained the importance of transparency in all of these conversations, including conversations involving NRP. A member stated that it is important to distinguish between a registered donor and next of kin authorization. For registered donors, the decision to donate has already been made, and so it is very important that the family has information about what this process will look like so that they know what to expect. For situations involving next of kin authorization, this member stated that disclosing to the family that donation is a possibility while they are thinking about the timing and whether to withdraw supports transparency, and that the purpose would be to provide information at that point and not solicit a decision. Another member added that at their hospital, the next of kin still

needs to authorize pre-mortem interventions necessary to proceed with the donation process for registered donors. The presenter responded that this is important to consider, and that variation in protocol does exist.

A member asked if this conversation can be initiated by donor hospitals, and the presenter responded that OPO staff are better positioned to initiate this conversation and that OPOs have worked hard to avoid having hospital staff discuss donation (for avoiding perception of conflict of interest and because OPOs are donation experts).

Members then discussed the usual process for how an OPO is involved in the discussions with families. A member asked if the OPO Committee is considering the triggers that hospitals have in place to involve the OPO, noting that if the OPO is apprised of where the family is in the decision-making process, involvement can be smoother. This member stated that these trigger points for involving the OPO may need to be sooner. The presenter responded that while the Committee has not discussed this at this point, that they will keep it in mind for project development. The Vice Chair stated that there are many studies that provide best practices for conversations about donation with the donor family.

A member stated that one solution to consider would be educating the family that withdrawal of life support may take more time than they think (depending on a variety of factors), as it seems that part of the problem is that families think that once they make the decision to withdraw, it will happen immediately. The presenter explained that many times, hospitals tell families that the process of withdrawal is fairly immediate, and that while this is a good idea, it may not be a full solution.

Three members volunteered to participate in the Workgroup for this project.

Next Steps:

The OPO Committee will engage with the Ethics Committee throughout the course of project development, and those members who volunteered to serve on the Workgroup will be contacted about next steps.

Upcoming Meeting(s)

- April 18, 2024

Attendance

- **Committee Members**
 - Andy Flescher
 - Sanjay Kulkarni
 - Sheila Bullock
 - Laura Butler
 - Andrew Courtwright
 - Laura Jokimaki
 - Keren Ladin
 - Lisa Paolillo
 - Ehab Saad
 - Lois Shepherd
 - Erica Stohs
 - Megan Urbanski
 - Felicia Wells-Williams
 - Sena Wilson-Sheehan
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Bryn Thompson
- **UNOS Staff**
 - Kieran McMahon
 - Cole Fox
 - Carlos Martinez
 - James Alcorn
 - Kayla Balfour
 - Kelley Poff
 - Kim Uccellini
 - Eric Messick
- **Other Attendees**
 - Dianne La-Pointe Rudow
 - Gloria Chen
 - Sandy Edwards
 - Laura Butler
 - PJ Geraghty
 - Rocky Daly