

**OPTN Ethics Committee
Meeting Summary
November 16, 2023
Conference Call**

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

Introduction

The Ethics Committee (“Committee”) met via WebEx teleconference on 11/16/2023 to discuss the following agenda items:

1. Welcome and Announcements
2. OPTN Expeditious Taskforce on Efficiency
3. Focus New Project Idea and Discussion

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

1. Welcome and Announcements

The Chair, Vice Chair, and staff welcomed members to the meeting and introduced the agenda.

2. OPTN Expeditious Taskforce on Efficiency

The Committee heard a presentation about the development of a new Taskforce to address organ non-use and allocations out of sequence.

Presentation summary:

On September 13th, an email communication went out announcing that the OPTN Board of Directors has approved the creation of a taskforce to study and improve the efficiency of organ usage and placement. Since then, the Taskforce has held a townhall to provide information to the community and provide a space for discussion (a recording is available), finalized Taskforce leadership and roster, and met in person on October 25th.

Staff provided some information about Taskforce composition and leadership and background information about the rationale behind creating the new approach to focusing on efficiency.

Taskforce key responsibilities include:

- Evaluate existing data and recommendations regarding system challenges and improvements.
 - Ad hoc Systems Performance Committee, NASEM Report, Presentations, Publications, Op/Eds, Regional Meeting, Committee Meeting and Board Meeting feedback, etc.
- Engage directly and frequently with the community to obtain data, feedback and suggestions.
 - Work closely with OPTN Committees.
 - Interviews, focus groups, webinars, meetings, etc.
 - Consider new ways of engaging the community and engage with both critics and supporters.
 - Pilot improvement opportunities, including data collection, when possible.

- Prioritize issues to address. Recommend both short-term improvements and long-term strategies to address larger challenges.
 - Encourage innovative approaches. Evaluate practical challenges and considerations, and ways to test possible solutions.
- Frequently update the Executive Committee and Board of Directors.
 - The Executive Committee and Board of Directors will be responsible for ensuring resources are available and alignment with the OPTN Strategic Plan.
 - OPTN Committees will be responsible for sponsoring any policy proposals.

Also, the development of continuous distribution by the OPTN Kidney and Pancreas Transplantation Committees will now proceed on a slower timeline to include some of these efficiency considerations within the model. Staff turned it over to a Committee member who has been appointed to serve on the Taskforce.

This member shared their experience of being on the Taskforce so far, noting that the Taskforce is focusing on bold aims and incorporating different voices and perspectives into their work.

Summary of discussion:

The Visiting Board Member added that they also serve on the Taskforce and that the work is exciting and will focus on criticism heard from the community and how best to prioritize solutions. The Chair added that it is promising to have both a Visiting Board Member and a member serving on the Taskforce. The Chair continued that one outstanding question is how the Taskforce will affect Committee projects.

Next steps:

The member who serves on the Taskforce will continue to update the Committee at regular intervals.

The Committee voted on the Normothermic Regional Perfusion (NRP) White Paper.

3. Focus New Project Idea and Discussion

The Committee discussed their new project idea, a white paper on access to living donation, and worked to focus the project and define the scope.

Presentation Summary:

The Chair began by recapping the Committee’s charge, the policy development process, OPTN strategic goals, and the goal of today’s meeting to focus the idea for project approval by the Policy Oversight Committee.

The Chair introduced the following discussion questions for the Committee to consider while discussing the idea:

- What is the problem statement?
- Why is this the right time to take this issue up?
- Why is it important for the OPTN to take a stance on this?
- What impact to members would this white paper have/how would it be used?
- Who is the target audience?
- How would this impact different populations?
- Ideas on how the white paper should be structured
- What is in the scope of this project? What would be considered out of scope for this project?
- Important literature to reference?

The Chair also recapped the problem statement that Committee leadership worked on in advance of the meeting for Committee discussion and refinement:

This white paper undertakes an ethical analysis of the implications of providing (tangible) incentives, and alternatively removing disincentives, for promoting equitable access to becoming a living donor. The project would mainly focus on the principles of utility, equity, and autonomy, and refer to some recent legislative proposals from different states (Massachusetts and New York) in order to illuminate the conceptual and ethically significant difference between “adding incentives,” on the one hand, and “removing disincentives,” on the other. While the former is arguably exploitative, inequitable, and even potentially in violation of the National Organ Transplant act of 1984 (NOTA), the latter is, by contrast, a move to remove equity barriers in a bid to make living donation something which is cost-neutral, a move which may also have a utility upside. Whether our system for encouraging living donation relies upon the provision of incentives, or the removal of disincentives, furthermore, bears on a prospective donor’s autonomy insofar as the idea in recruiting a living donor is to respect and enable their wish to donate (even if they come from under-resourced backgrounds) while in no way coercing them to do so. One of the notions under exploration in this paper is that living donation might be considered a privilege, which beckons the question: how can we make this privilege more accessible to groups who traditionally do not participate in living donation as frequently as others?

Summary of discussion:

The Committee workshopped the project idea.

A member expressed support for the project and scope as defined by leadership. Another member suggested including a section on those who do not meet the definition of brain death but whose families still want to donate, and the Chair noted that this is a good idea to revisit but may be a slightly different topic than this paper. The Vice Chair noted that this project needs to not just focus on kidney, but also address specifically living donors of livers. The Chair stated that perhaps a section of the paper should address living donation for livers. A member explained that the paper could address living donation by incarcerated people and financial resources associated with this. The Chair responded that this is an interesting question, but may be a separate topic from this paper.

A member stated that to them, NOTA is somewhat vague and this may be a good opportunity to clarify the definition of providing incentives versus removing disincentives. The Chair explained that NOTA is clear in what is not allowed, but that the paper could explain the considerations within the scope of the law. The Vice Chair asked if it would be within the scope of the project to suggest any revisions to NOTA, and staff responded that this is not within the scope of the Committee. The Chair explained that it is within the scope to explain how ethical principles support the existing text of NOTA.

The Vice Chair explained that a question for the project to answer is if providing true incentives is ethically justified. A member asked if the Committee could receive a presentation from Iran, who provides financial incentives for donation. The Chair and staff responded that expert presentations to the Committee can certainly be arranged, however, the Committee does need to consider that previously, the Committee tried to publish a paper on incentivization of living donation, but this was pulled due to concerns about authority and scope. So, this project idea would need to be separate and different from how that paper discussed these topics. The Chair explained that this paper needs to focus on making living donation accessible. A member added that the Committee could explore why different living donor programs have different rates of living donation.

To the question of why this is the right time, the Chair explained that this fits nicely with the work of the Taskforce, as focusing on living donation as a means to increase transplants is an important topic.

Another member added that there has been a big increase in kidney paired donation (KPD) and this would connect nicely.

Next steps:

This discussion will be summarized and presented to the Policy Oversight Committee in their December meeting for project approval.

Upcoming Meeting

- December 21, 2023

Attendance

- **Committee Members**
 - Andrew Flescher
 - Sanjay Kulkarni
 - Melissa Anderson
 - Lois Shepherd
 - Thao N. Galvan
 - Sena A Wilson-Sheehan
 - Megan Urbanski
 - Jen Dillon
 - Keren Ladin
 - Laura L Butler
 - Lois Shepherd
 - Laura Jokimaki
 - Ehab R Saad
 - Shelia Nichols Bullock
 - Erica Stohs
 - Lisa Paolillo
 - Carrie Thiessen
- **HRSA Representatives**
 - Marilyn Levi
 - Jim Bowman
- **SRTR Staff**
 - Bryn Thompson
- **UNOS Staff**
 - Kieran McMahon
 - Cole Fox
 - Rebecca Murdock
 - James Alcorn
 - Kristina Hogan
 - Laura Schmitt
- **Other Attendees**
 - SDeLair
 - Samantha Taylor