

OPTN Liver and Intestinal Organ Transplantation Committee

Meeting Summary

August 4, 2023

Conference Call

Scott Biggins, MD, Chair

Shimul Shah, MD, MHCM, Vice Chair

Introduction

The OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) met via Citrix GoToMeeting teleconference on 08/04/2023 to discuss the following agenda items:

1. Continuous Distribution: Medical Urgency Rating Scale Data Request
2. Public Comment Presentation: Operations and Safety Committee (Deceased Donor Support Therapy Data Collection)
3. Public Comment Presentation: Ethics Committee (Ethical Analysis of Normothermic Regional Perfusion)

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

1. Continuous Distribution: Medical Urgency Rating Scale Data Request

The Committee heard a presentation from Staff asking the Committee if they supported submitting the data request to compute the 90-day waitlist mortality rating scale for continuous distribution to be submitted to the Scientific Registry of Transplant Recipients (SRTR).

Summary of discussion:

Decision: The Committee supported the data request being submitted.

There was no further discussion.

Next steps:

Staff will submit the data request to SRTR.

2. Public Comment Presentation: Operations and Safety Committee (Deceased Donor Support Therapy Data Collection)

The Committee heard a presentation of the OPTN Operations and Safety Committee's proposal.

Summary of discussion:

Decision: The Committee supported the *Deceased Donor Support Therapy Data Collection* and provided feedback on ways it could be improved.

The Chair of the Liver and Intestine Committee asked about potential impacts to data mapping to which the Chair from the Operations and Safety Committee confirmed that it was discussed to ensure it would be mapped correctly. A member is concerned with consistent definitions for therapies and how they are

tracked. They are also concerned because not all programs are working on all the therapies listed in the proposal. The member recommended including a data field that specified if therapy was used prior to or after declaration of death, which is a current challenge with extracorporeal membrane oxygenation (ECMO) and normothermic regional perfusion (NRP) data. The Chair of the Liver and Intestine Committee asked how one would indicate therapies being started, stopped, and then started again. The Chair of the Operations and Safety committee said that he was unsure but would bring this feedback to the Operations and Safety committee to be discussed further.

Next steps:

Feedback will be summarized, and the Committee will post an official comment on the *Deceased Donor Support Therapy Data Collection* proposal on the OPTN public comment website.

3. Public Comment Presentation: Ethics Committee (Ethical Analysis of Normothermic Regional Perfusion)

The Committee heard a presentation of the OPTN Ethics Committee's white paper.

Summary of discussion:

Decision: The Committee supported the *Ethical Analysis of Normothermic Regional Perfusion* white paper and provided feedback on ways the analysis could be expanded upon.

The Chair of the Liver and Intestine Committee asked if the "last gift" concept was considered when analyzing the respect for persons principle, as they believe that this should be heavily weighted. The Vice Chair of the Ethics Committee said the Committee did not consider this principle specifically, but they acknowledge utility and the importance of the "last gift" when looking at NRP. They said the utility and last gift principle were both relevant, but if the Dead Donor Rule (DRR) is violated, then that is an overriding issue that needs to be reconciled and supersedes those principles. A member of the Committee said utility and the "last gift" concept is important, but it is also important to not violate the DRR. The member said it is okay to disclose tools and technology, such as the methodology behind NRP and answer any questions families and donors may have. They cautioned the Ethics Committee about overwhelming donors and families with extreme details about NRP, therefore balancing disclosure while still respecting the level of detail families want to receive is important with NRP. Another member, who is a donor family member, said that donor families can receive and process information, but if they are told that there is potential for the family member to be resuscitated, then they would struggle with the obligation they have to follow the individual's final wishes.

A member stated they have not heard of any data showing that there was enough blood flow to restore any brain function through NRP and emphasized that there is a difference between perfusion and brain function. The Vice Chair of the OPTN Ethics Committee said they acknowledge that despite there is blood flow, there may not be enough to restore brain function, and they considered how the Universal Declaration of Death Act (UDDA) is phrased. Specifically, the Ethics Committee was concerned about blood flow to the brain stem after death, and that being misaligned with requirements for death presented in the UDDA. Another concern that the Ethics Committee would like feedback on is if it is ethical to use perfusion as a surrogate for brain function. A member asked if the Ethics Committee considered if the level of cerebral perfusion pressure used for brain death is relevant and if it could be measured. The Vice Chair of the Ethics Committee said it was considered, as an intensivist had mentioned that after declaration of death and after the 5-minute period, there would be so much edema in the brain that there would be no meaningful brain flow, but it could potentially still be measured.

Next steps:

Feedback will be summarized, and the Committee will post an official on the *Ethical Analysis of Normothermic Regional Perfusion* white paper on the OPTN public comment website.

Upcoming Meetings

- August 18, 2023 @ 2:00 PM ET (teleconference)
- September 8, 2023 @ 2:00 PM ET (teleconference)
- September 15, 2023 @ 2:00 PM ET (teleconference)

Attendance

- **Committee Members**
 - Aaron Ahearn
 - Allison Kwong
 - Cal Matsumoto
 - Chris Sonnenday
 - Christine Radolovic
 - Colleen Reed
 - Dev Desai
 - Jennifer Muriett
 - Jennifer Lau
 - Kathy Campbell
 - Kym Watt
 - Neil Shah
 - Scott Biggins
 - Shimul Shah
 - Shunji Nagai
 - Vanessa Pucciarelli
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Jack Lake
 - Katie Audette
 - Nicholas Wood
 - Tim Weaver
- **UNOS Staff**
 - Betsy Gans
 - Cole Fox
 - Elena Liberatore
 - Erin Schnellinger
 - Joel Newman
 - Katrina Gauntt
 - Kayla Balfour
 - Kieran McMahan
 - Meghan McDermott
 - Megan Oley
 - Niyati Upadhyay
- **Other**
 - Alden Doyle
 - David Weimer
 - Sanjay Kulkarni
 - Ted Papalexopoulos