

OPTN Transplant Administrators Committee

Meeting Summary

August 29, 2023

Detroit, MI

Susan Zylicz, MHA, BSN, CCTC, Chair
Jason Huff, MSN, RN, FNKF, Vice Chair

Introduction

The OPTN Transplant Administrators Committee (the Committee) met in Detroit, Michigan on 08/29/2023 to discuss the following agenda items:

1. Welcome & Fiscal Impact Analysis Group Report
2. Public Comment Item *Concepts for a Collaborative Approach to Living Donor Data Collection*
3. Public Comment Item *Amend Adult Heart Status 2 Mechanical Device Requirements*
4. Public Comment Item *Continuous Distribution of Hearts Concept Paper*
5. Public Comment Item *Require Reporting of Patient Safety Events*
6. Public Comment Item *Ethical Analysis of Normothermic Regional Perfusion*
7. Public Comment Item *Efficiency and Utilization in Kidney and Pancreas Continuous Distribution*
8. Public Comment Item *Deceased Donor Support Therapy Data Collection*
9. Public Comment Item *Update on Continuous Distribution of Livers and Intestines*
10. Public Comment Item *Modify Organ Offer Acceptance Limit*
11. Open Discussion

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

1. Welcome & Fiscal Impact Analysis Group Report

The Committee participated in an icebreaker and then heard a staff update on the Fiscal Impact Analysis Group (FIG) report. This update included consolidated feedback received from members at previous meetings and potential changes to the next cycle's questionnaire. Committee members were also encouraged to reach out if they wished to join the FIG.

Summary of discussion:

No decisions made.

Next steps:

FIG will be scheduling meetings in October or November for the next cycle of public comment items that need a fiscal impact analysis.

2. Public Comment Item *Concepts for a Collaborative Approach to Living Donor Data Collection*

The Vice Chair of the Living Donor Committee presented their concept paper currently out for public comment "Concepts for a Collaborative Approach to Living Donor Data Collection."

Summary of discussion:

The Committee will provide comments and feedback in the form of a public comment posted on the OPTN website.

A member remarked on the difficulty of gathering this amount of data, stating that living donor programs are already stretched thin on current follow-up requirements, but look forward to seeing what the Scientific Registry of Transplant Recipient's (SRTR) impact on this might be when they take on the long-term follow-up. Members expressed interest in hearing the feedback and data on the SRTRs Living Donor Collective, specifically the response rate from those candidates who end up not donating for assorted reasons.

A member mentioned the idea that having hospital Electronic Medical Records (EMRs) which could interface with the OPTN/UNOS systems could help reduce the burden on transplant centers and programs as it would reduce some manual aspects of data input.

Another member highlighted the necessity of developing a robust definition of "evaluation" as it can vary from program to program what is included in the evaluation process. Additionally, members illuminated concerns that the data could be skewed towards those who become living donors, as they have already indicated responsiveness and a willingness to participate in long-term follow-up.

Next steps:

Staff will summarize the Committees feedback and submit a public comment to the OPTN website.

3. Public Comment Item Amend Adult Heart Status 2 Mechanical Device Requirements

The Chair of the Heart Transplantation Committee presented the policy proposal out for public comment "Amend Adult Heart Status 2 Mechanical Device Requirements".

Summary of discussion:

The Committee will provide comments and feedback in the form of a public comment posted on the OPTN website.

A member mentioned their concern about policy dictating drug usage to maintain status and highlighted the importance of exploring that risk. The Chair of the Heart Committee concurred that it is an important question and elaborated that a patient is still eligible for an exception if inotropic drugs are not an appropriate course of treatment.

Another concern was that there could be some congestion at Status 3 when moving patients down from Status 2. Additionally, a member voiced whether it had been explored that some Status 2 patients would need to be bumped up to Status 1. The Heart Committee Chair assented, stating that it is a relatively small group of patients and so interpreting that data is more difficult, but would be under consideration to move to Status 1 if medically necessary.

Next steps:

Staff will summarize the Committees feedback and submit a public comment to the OPTN website.

4. Public Comment Item Continuous Distribution of Hearts Concept Paper

The Chair of the Heart Transplantation Committee presented the concept paper out for public comment "Continuous Distribution of Hearts."

Summary of discussion:

The Committee will provide comments and feedback in the form of a public comment posted on the OPTN website.

A member mentioned their concern relating to how proximity would be measured, indicating that it is often more than mileage, but should also include access to flights/airports, charters, or other means of transportation. One member mentioned that from a logistical standpoint, drivable distance should perhaps take priority in the proximity discussion. The Heart Chair acknowledged this concern and stated the Heart Committee has been discussing this continuously. They also highlighted that there are a variety of factors at play, noting that the aim is to balance access, fairness, and sharing. It was also noted that distance/proximity is only a portion of the total allocation score, and other factors such as medical urgency could trump proximity.

Another member emphasized that sometimes hospitals will transfer potential donors to donor care centers, but the match run is based upon the original donor hospital which could create difficulties in proximity matching.

The Committee Chair mentioned that if heart centers are self-regulating outcomes, referencing an 11% median acceptance rate, whether there might be an opportunity with post-transplant survival as an attribute to also take heart utilization numbers into consideration. The Heart Chair assented that it is a valid concern, but not necessarily one that the Heart Committee can address, as that could fall more under the purview of regulatory bodies and can include other factors such as insurance.

Next steps:

Staff will summarize the Committees feedback and submit a public comment to the OPTN website.

5. Public Comment Item *Require Reporting of Patient Safety Events*

The Vice Chair of the Membership and Professional Standards Committee (MPSC) presented their policy proposal out for public comment “Require Reporting of Patient Safety Events.”

Summary of discussion:

The Committee will provide comments and feedback in the form of a public comment posted on the OPTN website.

The Chair brought up that “near misses” might be happening at a greater frequency than the data suggests and advises that broadening the definition could ensure collection of events that occur during the verification process. A member asked whether any transportation events would also count as “near misses” to which the MPSC Vice Chair informed the Committee that there are other projects looking at greater transportation issues which aim to address that.

Another member suggested that offering a 72-hour window for reporting might be more acceptable for non-critical events, allowing weekend staff to submit on a Monday in some cases. The Committee was advised that the 24-hour timeline suggested in the proposal aligns with current OPTN and HHS reporting requirements, but 72 hours would be taken into consideration.

One member queried whether considerations would be made when reviewing transportation events, as sometimes weather can cause delays. The MPSC Vice Chair affirmed that unavoidable or uncontrollable events would be screened out, but the main objective is to gather as much data as possible.

Members discussed the clarity of language surrounding “sanctions,” as the term can vary state by state. They also mentioned concerns that a “professional body” requires further definition to prevent any misunderstanding of the policy.

A member aimed to clarify whether the required reporting would create an additional step in reporting of living donor events, indicating that it would be duplicative, as this information is already being reported in the Patient Safety Portal. It was clarified for the Committee that similar feedback has been received and the proposal will be reviewed to prevent any duplication of efforts. Additionally, this proposal expands the living donor reporting requirement to all living donors of any organ type, while prior it was only liver and kidney.

Next steps:

Staff will summarize the Committees feedback and submit a public comment to the OPTN website.

6. Public Comment Item *Ethical Analysis of Normothermic Regional Perfusion*

The Chair of the Ethics Committee presented their white paper currently out for public comment “Ethical Analysis of Normothermic Regional Perfusion.”

Summary of discussion:

The Committee will provide comments and feedback in the form of a public comment posted on the OPTN website.

Members discussed the importance of showing the difference between abdominal normothermic regional perfusion (A-NRP) and thoracic-abdominal NRP (TA-NRP) in the paper, as well as the difficulty of knowing how much information is too much when discussing donations decisions with donor families. A member brought up that there are varying degrees of what donor families wish to hear about the clinical process of donation and expressed concern about what OPOs could be required to disclose. Additional points were brought up relating to how OPOs can speak with donor families, as there is policy regarding when an OPO can address a donor family. It was suggested that consistency be attained between current OPTN policy, OPO current practice, and the Ethics white paper.

The Committee also expressed concern with the term “informed decision-making” as it is inconsistent with how donation is approached as that language is used for living donors and patients.

One member suggested referencing a recent piece that involved quantitative research into the reperfusion of brainstem concerns the white paper references. The Ethics Chair accentuated that any additional research is beneficial, and the Ethics Committee would relish the opportunity to continue the discussion of NRP as the procedure develops.

Next steps:

Staff will summarize the Committees feedback and submit a public comment to the OPTN website.

7. Public Comment Item *Efficiency and Utilization in Kidney and Pancreas Continuous Distribution*

The Vice Chair of the Kidney Transplantation Committee presented their Request for Feedback on “Efficiency and Utilization in Kidney and Pancreas Continuous Distribution” which is out for the public comment cycle. The Vice Chair spoke specifically about the Dual Kidney policy changes that could take effect with Kidney-Pancreas CD.

Summary of discussion:

The Committee will provide comments and feedback in the form of a public comment posted on the OPTN website.

Members suggested that having an experience criteria in place for centers before they start receiving dual kidney offers, they need to have a proven record of performing dual kidney transplants. A member offered that instead of basing policy changes off a percentage of patients for dual kidney, it should be based on a percentage of centers able to perform dual kidney transplants.

Next steps:

Staff will summarize the Committees feedback and submit a public comment to the OPTN website.

8. Public Comment Item *Deceased Donor Support Therapy Data Collection*

The Operations and Safety Committee (OSC) Vice Chair presented their policy proposal out for public comment, “Deceased Donor Support Therapy Data Collection.”

Summary of discussion:

The Committee will provide comments and feedback in the form of a public comment posted on the OPTN website.

A member asked whether there is a field to identify whether NRP was utilized for the donor, or if ECMO support encompasses it as an option. They were assured that the Organ Procurement Organization (OPO) Committee has a project in the works that would include NRP as a support option.

Members agreed that there would be no significant issues with collecting the support therapy data as it is generally already collected but would need clarity on where to input it if, as in the case of NRP, the data fields are not available on the OPTN systems yet.

One member recommended that the end date field state “on or before cross-clamp date” instead of simply “before cross-clamp date” to be more accurate in their reporting.

Next steps:

Staff will summarize the Committees feedback and submit a public comment to the OPTN website.

9. Public Comment Item *Update on Continuous Distribution of Livers and Intestines*

The Liver and Intestine Committee Vice Chair presented their public comment item “Update on Continuous Distribution of Livers and Intestines.”

Summary of discussion:

The Committee will provide comments and feedback in the form of a public comment posted on the OPTN website.

A member queried as to how the Liver Committee was looking into travel efficiency. The Vice Chair commented that they are utilizing 150 NM as their metric for driving versus flying, as every organ will be different regarding efficiency. This member pressed as to whether cost is being viewed as an outcome, to which the Vice Chair responded that while it is an important topic, cost is too broad with too much imbalance associated for it to be an acceptable outcome or criteria in continuous distribution.

Next steps:

Staff will summarize the Committees feedback and submit a public comment to the OPTN website.

10. Public Comment Item *Modify Organ Offer Acceptance Limit*

The Vice Chair of the Organ Procurement Organization (OPO) Committee presented their policy proposal currently out for public comment “Modify Organ Offer Acceptance Limit.”

Summary of discussion:

The Committee will provide comments and feedback in the form of a public comment posted on the OPTN website.

Members discussed the concerns of non-use of livers, and whether an additional concern is the allocation out of sequence that can occur in some scenarios. A member brought up that it is still possible for an acceptance to be pulled at the last minute, wondering if this policy proposal was going to eliminate such situations. The Vice Chair commented that it might not eliminate such situations, but is a start in reducing them, also emphasizing the importance of communication between OPOs and transplant centers to avoid such events from the beginning.

A member highlighted that there are many nuances still to be considered with only allowing one organ offer at a time, especially for liver, as sometimes a center will hold on to an offer until the organ is in the operating room and the center receives more information about size, biopsy, etc. Members agreed that there should be some exceptions for high-risk patients, such as those with a higher MELD/PELD score and suggested that waitlist mortality also be a consideration under this policy proposal.

Next steps:

Staff will summarize the Committees feedback and submit a public comment to the OPTN website.

11. Open Discussion

The Committee discussed ideas and items that were raised prior to the meeting and during the meeting.

Summary of discussion:

No decisions made, simply a discussion

Meeting Summary:

A member mentioned their concern that it is difficult and can create errors when trying to distinguish between the number '0' and the letter 'O' within UNOS ID numbers. The member raised the question of whether there had been any discussions regarding the removal of these characters. Another member pointed out that an algorithmic process was causing sequential assignments of numbers, which could potentially result in human errors. They emphasized the need for better number assignment to mitigate this problem. One member suggested the implementation of a good, randomized number format to prevent mixing with other characters, along with advocating for longer numbers. There was also a suggestion to incorporate leading zeros to address the confusion between '0' and 'O.' Additional concerns were expressed about potential misinterpretations of 'B' versus '8.'

It was proposed to send this feedback to the Customer Advocacy team for further consideration.

A member sought feedback on a letter related to vessels and storage. They mentioned that their program was receiving notifications of non-compliance. UNOS Staff clarified that this issue was part of a series of projects spanning multiple committees. The MPSC has referred such a project to the

Operations and Safety Committee (OSC) for further evaluation. Additionally, members discussed the potential for a collaboration between the Committee and OSC on the project as it develops.

Next steps:

Staff will follow up on the UNOS ID numbers' differentiation difficulties with the Customer Advocacy team and let the Committee know about collaboration opportunities with other committees on projects such as the storage of vessels.

Upcoming Meetings

- September 25, 2023
- October 23, 2023
- November 27, 2023

Attendance

- **Committee Members**
 - Susan Zylicz
 - Christopher Wood
 - Dorrie Dils
 - Luke Preczewski
 - Emily Warren
 - Laura O'Melia
 - John Gutowski
 - Brian Cruddas
 - Katherine Dokus
 - Kay Shields
 - Kristin Smith
 - Charles Zollinger
- **HRSA Representatives**
 - Shelley Grant
- **UNOS Staff**
 - Stryker-Ann Vosteen
 - Lindsay Larkin
 - Delaney Nilles
 - Lauren Mauk
 - Laura Schmitt
 - Alex Carmack
 - Meghan McDermott
 - Angel Carroll
 - Kristina Hogan
 - Eric Messick
 - Cole Fox
 - Rebecca Brookman
 - Kieran McMahon
 - Joann White
 - Kayla Temple
 - Kayla Balfour
 - James Alcorn
 - Katrina Gauntt
- **Other Attendees**
 - Arpita Basu (Vice Chair Kidney Committee)
 - Lori Markham (Vice Chair OPO)
 - Shimul Shah (Vice Chair Liver Committee)
 - Kim Koontz (Vice Chair OSC)
 - Andrew Flescher (Chair Ethics Committee)
 - Scott Lindberg (Vice Chair MPSC)
 - Stevan Gonzalez (Vice Chair Living Donor Committee)
 - Rocky Daly (Chair Heart Committee)