

Thank you to everyone who attended the Region 11 Summer 2023 meeting. It was great seeing people in-person and still having an option for you to join virtually. We plan to continue providing both options.

Regional meeting [presentations and materials](#)

**Public comment closes September 19!** [Submit your comments](#)

The sentiment and comments will be shared with the sponsoring committees and posted to the OPTN website. Comments from live discussion and electronic submissions are included in this summary.

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## Non-Discussion Agenda

### Clarification of OPO and Living Donor Hospital Requirements for Organ Donors with HIV Positive Test Results

#### *OPTN Disease Transmission Advisory Committee (Ad Hoc)*

- Comments: A member commented that this is an important topic and these organs will go unnecessarily underutilized if clear guidelines are not established to confirm when a test is thought to be a false positive that it was indeed wrong and the patient is negative and/ or given that there are effective medications, we need to remove the stigma and accept that HIV is a treatable infection and that in this day and age it is probably inappropriate to make HIV transmission a "never event". Another member agreed with more clarification of results to avoid false positives.

### Continuous Distribution of Hearts Concept Paper

#### *OPTN Heart Transplantation Committee*

- Comments: A member commented that they support all allocation efforts that improve the efficiency and efficacy of utilization for donated hearts; this consideration should be assessed for all potential allocation changes.

### Deceased Donor Support Therapy Data Collection

#### *OPTN Operations and Safety Committee*

- Sentiment: **5 strongly support, 4 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose**
- Comments: A member commented that they agree with the additional data collection as long as definitions are clear and universal.

### Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Deceased and Living Donor Evaluation

#### *OPTN Disease Transmission Advisory Committee (Ad Hoc)*

- Sentiment: **7 strongly support, 3 support, 2 neutral/abstain, 1 oppose, 0 strongly oppose**
- No comments

## **Remove CPRA 99-100% Form for Highly Sensitized Kidney Candidates**

*OPTN Histocompatibility Committee*

- Sentiment: **5 strongly support, 3 support, 4 neutral/abstain, 0 oppose, 2 strongly oppose**
- Comments: A member agreed with removing this and said it is an unnecessary barrier to transplant.

## **Update Guidance on Optimizing VCA Recovery**

*OPTN Vascularized Composite Allograft Transplantation Committee*

- Sentiment: **4 strongly support, 6 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose**
- No comments

## **Update HLA Equivalency Tables 2023**

*OPTN Histocompatibility Committee*

- Sentiment: **5 strongly support, 6 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose**
- No comments

## **Update on Continuous Distribution of Livers and Intestines**

*OPTN Liver & Intestinal Organ Transplantation Committee*

- Comments: A member commented that they support all allocation efforts that improve the efficiency and efficacy of utilization for donated livers and intestines; this consideration should be assessed for all potential allocation changes.

## **Discussion Agenda**

### **Efficiency and Utilization in Kidney and Pancreas Continuous Distribution Request for Feedback**

*OPTN Kidney & Pancreas Transplantation Committees*

- Comments:
  - Dual Kidney
    - Several members commented that dual kidneys need to be offered sooner to improve utilization and that the process for expedited placement should be formalized and allow the OPOs more discretion. A member recommended using existing data to predict the probability of a single kidney being turned down and using that as the threshold for when they are offered as dual kidneys. Another member commented that dual kidney allocation is underutilized. In an online poll, over half respondents agreed that a combination of donor criteria and offering the kidney as a single first should be considered. The majority of respondents agreed that less than 50% of the match run should be exhausted before moving to dual allocation.
  - Mandatory KP shares
    - A member commented that consideration should be made for kidney-alone pediatric candidates who are increasingly disadvantaged by mandatory kidney sharing with multiple organ adult candidates. Mandatory KP sharing further

than currently experienced should occur only after pediatric candidates are offered a kidney. Another member commented that mandatory pancreas share should include other organ combinations as well as with kidney and allocating the pancreas with a liver and intestine or a modified multi-visceral should be highly prioritized due to the many other limitations in access to organs for this unique population of recipients.

- Pancreas medical urgency
  - Recommendations from members for pancreas medical urgency included hypoglycemic unawareness, uncontrolled diabetes with multiple DKA events, and that it should only apply to Type 1 diabetics with a low BMI and low insulin requirement with a history of hypoglycemic unawareness.

## **Amend Adult Heart Status 2 Mechanical Device Requirements**

### *OPTN Heart Transplantation Committee*

- Sentiment: **3 strongly support, 5 support, 5 neutral/abstain, 0 oppose, 1 strongly oppose**
- No comments

## **Require Reporting of Patient Safety Events**

### *OPTN Membership & Professional Standards Committee*

- Sentiment: **8 strongly support, 6 support, 1 neutral/abstain, 0 oppose, 0 strongly oppose**
- Comments:
  - Multiple members agreed with requiring reporting for living donors placed on the wait list for any organ within two years after donation. Members also agreed that the transportation events included in this proposal as required reports are appropriate.
  - There was significant discussion about delays and errors in transporting organs and many agreed that there is variability in the quality of courier services. Members recommended tracking delays and other quality issues with couriers. A member stressed the importance of coordination before the organ is sent to decrease errors and that when there is a delay with transportation, kidneys should be monitored for delayed graft function.
  - A member commented that uniformity in reporting is welcome as long as it is not punitive and another member stated that there should be a single reporting mechanism for both OPTN and HRSA and if the information comes from sharing of reporting between centers and HRSA who then informs UNOS, that is acceptable and preferable to requiring duplicative reporting

## **Modify Organ Offer Acceptance Limit**

### *OPTN Organ Procurement Organization Committee*

- Sentiment: **5 strongly support, 3 support, 1 neutral/abstain, 3 oppose, 3 strongly oppose**
- Comments:
  - Multiple members commented that high MELD and status 1 candidates should be able to have more than one acceptance to improve their chance of receiving a timely transplant as a delay, such as length of time to O.R., could be life threatening.
  - Multiple members agreed there should also be exceptions in the case of an offer from a DCD donor as only 50% of DCD cases proceed to donation and also to avoid discouraging programs from accepting DCD offers and potentially lead to increased non-utilization.

- Multiple members commented that because there is often an extended time period between acceptance and OR time, the official acceptance of the organ should occur at some standardized timestamp before OR. Some members commented that 4 hours before OR would be acceptable and others thought that was too close to OR time and recommended 6 hours to allow time for reallocation.
- A member commented that because of the time between offer acceptance and a scheduled OR time, there should be a backup plan for the organ, including expedited placement or machine perfusion to ensure the liver is transplanted.
- A member commented that because lungs can deteriorate over time, they support the idea of being able to accept two offers for higher status patients.
- A member commented that a program should only be able to hold one primary acceptance and gave an example in which a liver is turned down late because the program was holding onto two primary acceptances and by the time the second offer is turned down, the organ has too much cold time to reallocate.
- A member commented that holding more than one offer for a patient increases the risks for non-utilization especially in areas where local transplant programs are unable or unwilling to recover organs with short notice; a program should accept the organ with the best chance of successful transplantation for their patient but should not keep other organs from utilization for other recipients.

## **Concepts for a Collaborative Approach to Living Donor Data Collection**

### *OPTN Living Donor Committee*

- Comments:
  - Several members commented that this has the potential to increase burden to transplant programs especially if it included potential donors ruled out before being seen. Members encouraged a universal database, automated data extraction, and incorporating PCPs/other healthcare providers into the process.
  - A member commented that data collection on living donors is important to their post op care.
  - A member stated that this is important work and that it's incumbent upon us to know and be able to share outcomes beyond 2 years. They added that collaboration with SRTTR will make the pool being followed bigger and more relevant and that they have more tools for long-term follow up than transplant centers do and even short-term follow up has been difficult for transplant centers.
  - A member commented that they support the addition of analyzing barriers to donation.
  - A member commented that it would be helpful to see the knowledge gaps that are intended to be filled, what patients will be selected for comparison, what type of analysis will be used, etc. to be sure the effort is worthwhile. They asked if those declined for medical reasons are the right comparator for outcomes and are those responding a biased population?
  - Members commented that this data collection adds risk for the potential donor and the OPTN by housing PHI for patients no longer connected to the system and housed by a third party; whether or not this would require IRB review should be looked at carefully.

## Ethical Analysis of Normothermic Regional Perfusion

### *OPTN Ethics Committee*

- Sentiment: **4 strongly support, 2 support, 5 neutral/abstain, 3 oppose, 1 strongly oppose**
- Comments:
  - Several members commented that after death is declared, NRP perfuses organs, but does not reverse death. They commented that it leads to increased utilization and improved graft function.
  - There were multiple recommendations for the Ethics Committee to separate their recommendations for Thoracoabdominal versus Abdominal only NRP. As the ethical concerns are different and by combining them, the committee adds to the confusing information shared with people who do not understand the differences.
  - Members commented that there is an obligation to give the family details of NRP, but balance this with their loved one's/their decision to donate. A member commented that donation is governed by gift law and requires authorization, either next of kin or first person, but not informed consent and questions why the recovery process would change that. They also questioned if donation is first person authorized, who would be responsible for consent, particularly if the family has chosen to not participate in the process.
  - A member commented that they support ongoing data collection and ethical analysis and at this time their center is not participating in NRP.

## Updates

### **Councillor Update, OPTN Patient Affairs Committee Update, OPTN Membership and Professional Standards Committee Update, Member Quality Update, and Policy Oversight Committee Update**

- No comments

### **OPTN Executive Committee Update**

- Comments:
  - A member commented that the change in CMS metrics and availability of donors should be incorporated when presenting the numbers that show an increase in transplants.
  - A member suggested that the OPTN should consider providing information on the requirements for security training but allow the programs themselves to facilitate the training.
  - A member commented that the system's inefficiencies contribute to allocation out of sequence when attempting to place a challenging organ. This member added that programs should commit to early offers to decrease ischemic times. He suggested the use of predictive analytics to guide programs' decision making when organs are traveling longer distances.

### **OPTN Strategic Planning Feedback Session**

- Attendees participated in small group discussions in person and online participants had the opportunity to share feedback in an interactive tool online. The following is a summary of these exercises:
  - Members were presented with five potential strategic goals, asked to identify their top three, and also asked to identify missing themes.

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- Increase patient engagement through education and transparency, increase transplants, increase donors and available organs for use, maximize the value of organs and increase post-transplant quality of life, and improve allocation efficiency all received support as one of the top three by at least one group.
- Improve organ allocation, increase transplants, and increase donors and available organs for use received the most support as top three goals.
- Members identified increase equity and increase utilization as additional themes.
- Members had suggestions for improving allocation efficiency including OPOs having a timeline to have all organ information available, transportation improvements, and standardized thresholds for when to offer organs out of sequence
- A member commented that for increasing donors, the goal should be to increase donors that are good candidates for the best outcomes and to increase donors and decrease non-use at the same time. Another member commented that standardizing biopsies is important to assess the quality of organs.
- A member commented that the five proposed strategic goals should be everyone's core values and incorporated in everything that we do.