OPTN

Thank you to everyone who attended the Region 5 summer 2023 meeting. It was great being back 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.

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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: This was not discussed at the meeting, but attendees were able to submit comments with their sentiment. Attendees commented that they were in favor of the requirements, agreed with the proposal's intent, and agreed there is a need for more guidance.

**Continuous Distribution of Hearts Concept Paper**, *OPTN Heart Transplantation Committee*

- Comments: Attendees commented that continuous distribution allocation is a good goal, offered strong support for the paper, and said this is an interesting concept to increase heart transplants. Another attendee recommended to include a weighting of HLA matching, because data suggest there is better long term survival when there are 0 or 1 DR mismatches.

**Deceased Donor Support Therapy Data Collection**, *OPTN Operations and Safety Committee*

- Sentiment: **8 strongly support, 13 support, 1 neutral/abstain, 1 oppose, 0 strongly oppose**
- Comments: For donors who are on dialysis the form should indicate whether dialysis is intermittent or continuous.

**Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Deceased and Living Donor Evaluation**, OPTN *Disease Transmission Advisory Committee (Ad Hoc)*

- Sentiment: **11 strongly support, 13 support, 1 neutral/abstain, 0 oppose, 0 strongly oppose**
- Comments: Attendees agreed with standard evaluation guidelines and support such considerations.

**Remove CPRA 99-100% Form for Highly Sensitized Kidney Candidates**, *OPTN Histocompatibility Committee*

- Sentiment: **8 strongly support, 12 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose**
- Comments: An attendee supported removal of the CPRA 99-100% form for highly sensitized kidney candidates because the form's intent and utility in clinical practice does not align. There are already standards in place that HLA data entered into UNOS is reviewed and verified.

**Update Guidance on Optimizing VCA Recovery**, *OPTN Vascularized Composite Allograft Transplantation Committee*

- Sentiment: **6 strongly support, 10 support, 7 neutral/abstain, 0 oppose, 0 strongly oppose**
- Comments: No comments were submitted on this update.

**Update HLA Equivalency Tables 2023**, *OPTN Histocompatibility Committee*

- Sentiment: **6 strongly support, 16 support, 0 neutral/abstain, 0 oppose, 0 strongly oppose**
- Comments: An attendee inquired about the rationale in Table 4-2, whether there was concern this will create confusion; for example, one can select both A*01:01 or A*01:01P—why not just use the P group. A*32:04 is listed as matched equivalent to A3. Yet, this allele bears sequences (eplets 76ESI, 81ALR) not present in A3 but present in other A32 and A25, etc.

**Update on Continuous Distribution of Livers and Intestines**, *OPTN Liver & Intestinal Organ Transplantation Committee*

- Comments: No comments were submitted on this update.

## Discussion Agenda

**Efficiency and Utilization in Kidney and Pancreas Continuous Distribution Request for Feedback**, *OPTN Kidney & Pancreas Transplantation Committees*

- Comments: An attendee pointed out that donor criteria can change throughout the donation process, and as a result match runs should not be static. The attendee suggested that match runs should be able to evolve as donor information becomes available. Another attendee commented that while KDPI may be a good indicator of a kidney's quality, as time after cross-clamp increases, the kidney's quality decreases, which should have a corresponding impact on the kidney's allocation. The member suggested that OPO's should not begin allocating kidneys after cross-clamp and offers should not be made in the middle of the night.

  During the meeting the attendees participated in group discussion sessions and provided feedback on one of three questions:

  - **Dual Kidney Eligibility Requirements**
    - Several attendees suggested that the requirements should be based on cold ischemic time, or a certain number of hours within going to the operation room (6 hours), on the sole organ allocation list, then at a pre-designated time on the sole organ allocation list, switch over to dual kidney allocation list.
    - Attendees pointed out the importance of having another dual match run, one for centers that have a history performing dual transplants and one for those centers who do not. Centers who don't perform duals should be bypassed until they opt in and perform one (efficiency). The percentage of match run centers should be used, not the candidates. Another attendee suggested to only offer to centers that have a history of transplanting at least one dual kidney transplant

beyond a certain distance, which will leave opportunity for centers to accept a dual only within a certain distance of a center.

- There should be three corresponding refusal codes: one to decline single organ offer, one for dual organ offers, and one for refusal code that says no to single offers but will accept dual organ offers. Another attendee center requested two refusal codes: one to accept as both single or dual, and another to refuse for single but accept as dual. The center also suggested that biopsy results could trigger reallocation as dual off later in the allocation process.
- It was also suggested to use donor criteria (determined by SRTR) for very difficult to place kidneys that have at high risk of discards, and not have 56 different definitions. The member recommended to not use the percentage of candidates that have refused an offer but rather the percentage of centers that have declined the organ (the top of the match run list can be dominated by a local centers with very large waitlists).
- A member expressed concern about allowing acceptance criteria metrics to be applied to a dual allocation list and organ utilization used in this manner is too variable for center measurement.
- The majority of online attendees supported the use of a combination of donor criteria and offering the kidney first for the policy definition of when an OPO may begin allocation kidneys as dual.
- For what percentage of the match run should be offered and decline the primary offer before the OPO can move to dual allocation, approximately 1/4$^{th}$ of online attendees supported “50-75%” category, and approximately 1/3$^{rd}$ of online attendees supported the “less than 50%” category, and approximately 1/3$^{rd}$ of online attendees supported the "75-90+%” category.

- **Pancreas Medical Urgency clinical guidance**
  - Many attendees suggested that pancreas medical urgency should be utilized for type 1 diabetic candidates, there should be standardized exceptions for unaware hyperglycemic candidates for pancreas only, and standard exception form for transplant professionals to utilize.
  - Several attendees suggested that unaware hyperglycemic candidates should be the *only* candidates who receive a pancreas medical urgency exception.
  - An attendee suggested the exception should also include a category for diabetics who have been diabetic since childhood. The attendee pointed out the challenge would be around hyperglycemic awareness.
  - An attendee suggested the following clinical criteria for candidates who qualify for pancreas medical urgency: inpatient medical status, lack of vascular access, or inability to support with parenteral nutrition, hypoglycemic unawareness, and other kidney.
  - Several attendees commented that medical urgency scenarios should include lack of vascular access.
  - One member did not support the pancreas medical urgency exception pathway.
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- A center stated they disagreed with the facilitated pancreas policy as proposed. They explained that typically the pancreas match run contains a small number of centers and recipients; and that it is rare to not have a high quality pancreas placed using the traditional match run prior to the donor being in the operating room. The routine bypass of patients at non-facilitated centers by nature disadvantages these patients from equal access to donor organs. This is particularly true for the sensitized patient population, who are already limited in their access to donor pancreata due to the high sensitization. Finally, bypassing "non-facilitated" centers disadvantages all candidates on the waitlist at those centers from access to pancreas transplant, while also discouraging and impairing growth of upstart pancreas programs. If enacted, these members believed the proposed policy will provide an unjust advantage to waitlisted candidates at higher-volume centers, irrespective of their waitlist time or sensitization. They believed the proposed policy is inconsistent with the established criteria for prioritization of kidney-pancreas match run.

- **Mandatory Kidney Pancreas Shares Threshold**
  - A patient listed for KP or candidate for KP but no longer has vascular access options should be amongst candidate characteristics considered in determining the mandatory KP shares threshold.
  - A KP should not pull ahead of pediatric candidates.
  - Hypoglycemic awareness should be the medical criterion for higher priority and mandatory KP share. There should be a standard exception form developed to establish the number, frequency, and severity of the episodes and standardized criteria to meet in order to meet the threshold.

**Amend Adult Heart Status 2 Mechanical Device Requirements**, *OPTN Heart Transplantation Committee*

- Sentiment: **6 strongly support, 11 support, 5 neutral/abstain, 3 oppose, 0 strongly oppose**
- Comments: Many attendees supported the status 2 change and offered suggestions for the committee. An attendee suggested the Committee consider using machine learning, using criteria that aren't "gameable". They pointed out there are a lot of decisions that drive deciding who receives a heart transplant (such as choosing to wean or not to wean pressors, or choosing to implant an impella heart pump). The attendee suggested adding inotropic with an intra-aortic balloon pump (IABP). An attendee commented that with status 2, they are seeing a lot of stability with these therapies. They pointed out that status 2 patients are not all the same and has more granularity. Several attendees thought the proposed status 2 change will yield more exceptions and noted that inotropes are not safe for many high-risk patients. Several attendees suggested the committee tighten the criteria for status 2. An attendee suggested that allocation priority should be based on patient health status as opposed to treatment protocol. The attendee supported the proposal because it may reduce unneeded interventions, but suggested rethinking the approach. This proposal implies there is 'gaming' of the system by centers putting in IABP/Impella devices 'unnecessarily'. A center expressed concern that the committee is

- essentially dictating clinical care - sometimes in circumstances as noted by others where it may be dangerous to do so. (i.e. patients prone to arrhythmias in response to pressors). The proscription of clinical care and the determination of medical criteria based on the treatments candidates receive has many pitfalls. They thought better predictors of both short term and long term waitlist mortality ought to be substituted in place of simply ranking patients by the treatment of such patients. An attendee pointed out that inotropes are often not safe in many high-risk patients waiting for heart status where temp devices could be helpful when inotropes are not (for candidates prone to arrhythmias and candidates with already poor RVs).

**Require Reporting of Patient Safety Events**, *OPTN Membership & Professional Standards Committee*

- Sentiment: **6 strongly support, 16 support, 1 neutral/abstain, 1 oppose, 1 strongly oppose**
- Comments: An attendee commented they were pleased by recent efforts to share information about events in the hopes of preventing similar events elsewhere. An attendee asked for specifications, specifically for reporting requirements for sanctions taken by professional bodies. There is lack of definition as to what includes a "sanction" and what an "other professional body" may entail. This is very concerning, especially in California, as this can mean many things. The attendee explained that it is unclear at which points in the current proposal when centers must report this. Often there are multiple bodies investigating issues, including medical boards, public health departments, amongst others, which can take a very long time. MPSC may want to take a step back and address those issues and bring that part of the proposal back forward. The attendee thought it would be beneficial for the community to know and understand when a report is issued and when HRSA is notified and what potential actions HRSA may take, specifically with sanctions. An attendee pointed out that transportation is a large barrier at their center since it is in a largely rural setting, and some of these difficulties that clearly impact patient care should be reported to better understand the issue.

**Modify Organ Offer Acceptance Limit**, *OPTN Organ Procurement Organization Committee*

- Sentiment: **7 strongly support, 7 support, 1 neutral/abstain, 5 oppose, 5 strongly oppose**
- Comments: Region 5 strongly supported the committee investigating the reasons for late declines and how to reduce or eliminate the late declines. While several members expressed support for the intention of the proposal they believed the real problem is with late declines. They explained that it is a huge problem for an OPO to have a late decline. To not allow a transplant center to accept two offers for the same recipient may result in candidate death because the offer may not come through for many reasons. They suggested to focus on how transplant centers can collaborate, be transparent, and increase communication. Late declines may result in someone far down the match run to receive an organ, but there are ways to mitigate this. They suggested to utilize the hard backup, and make transplant centers accountable for being a hard backup. This would mean that the transplant center has to communicate how likely or unlikely they are to accept the offer. If a simultaneous offer exists, then the transplant center should communicate that to the OPO. If the hard backup is because

the first donor is questionable, if the OPO has not gotten a biopsy and that might not occur, the OPO should tell the transplant center hard backup why they're a hard backup. They suggested the solution is more consistency across OPOs, more accountability and transparency, while also not limiting the clinician's ability to provide the best patient care. An attendee requested the committee to define who are "higher status candidates".

- Attendees expressed concern about DCD offers and suggested an exception pathway for pediatric candidates. An attendee suggested that the Committee investigate the details of the late decline, and even require more robust justification for the decline, and determine if certain centers are declining more than others and why. Several attendees pointed out that pediatric candidates may be impacted more severely by late declines and that the committee should investigate.
- A member suggested that an additional metric should be to see is how long it takes an OPO to deliver the final necessary data to determine acceptance, since one factor in late declines is delays in obtaining data (i.e. pathology).
- A member explained this proposal is the most equitable solution at this time. Whether late declines are related to multiple offers, this causes out of sequence allocations. This is a big problem and its disadvantaging patients right now. Patients are being bypassed because we can't get these livers to the next appropriate patient on the list.
- An attendee said this will impact the sickest patients and suggested eliminating 2 offers going under 8 hours. Another suggestion, that policy should be modified to exclude donation after cardiac death (DCD) offers and patients who are extremely sick like status 1 candidates and candidates with MELD >35. Several attendees suggested an exception or alternate pathway for DCD donors since they may not end up donating and therefore are less of a "guaranteed" organ. Several attendees suggested to put late declined organs on a pump in order to offer additional time for re-allocation.
- A member suggested that UNOS and OPOs should document the frequency of late declines and publish data by center. The centers that participate in late declines frequently need to be examined. The ability to accept two livers for a very sick patient needs to be preserved (where it would be okay for lower MELD candidates but most simultaneous offer acceptances occur in candidates highest on the match run). The magnitude of the 'problem' of simultaneous offers is small. The problem of late declines is far larger than this population. As the MPSC has suggested, track and report rates of late declines by transplant centers: disseminate OPOs that do or do not do their best to avoid late declines (for example, some OPOs greatly facilitate pre procurement liver biopsies where as other OPOs never offer pre-procurement biopsies); increase transparency, and utilize "hard back-ups" (offer details about "hard back-ups" to all centers).
- Another attendee pointed out that accepting two donor offer simultaneously for a recipient is very reasonable. The attendee explained that historically, the acceptance limit was even greater than two donor offers. The attendee believed that OPOs should take more initiative and responsibility to inform the transplant centers who are below the primary recipient, that the primary recipient has two offers, and that the transplant centers should be ready to accept the 2nd organ if turned down by the primary candidate.

**Concepts for a Collaborative Approach to Living Donor Data Collection***, OPTN Living Donor Committee*

- Comments: Several attendees agreed with the concept, intent of the proposal, and collecting long term data on living donor outcomes. An attendee supported the proposal and suggested a focus on healthcare disparities. Specifically, an attendee commented that the definition is inaccurate for living donors. They explained the proposal mentions that different programs have different operations with screening, especially with MKR, and the variation will lead to data collection disparities. The attendee suggested the committee look at existing guidelines, and believed that whether or not the donor is physically seen, on site, is irrelevant. Identifying barriers moving forward by taking lab values before coming into the clinic is helpful. Several attendees suggested the committee focus on defining who is a living donor and creating a narrow definition for a living donor.

**Ethical Analysis of Normothermic Regional Perfusion*, OPTN Ethics Committee***

- Sentiment: **8 strongly support, 10 support, 6 neutral/abstain, 0 oppose, 1 strongly oppose**
- Comments: The vast majority of region 5 supported this analysis. An attendee commented that explaining the NRP procedure to some donor families could be overwhelming to the family. They explained the donor conversation is a delicate conversation and is not just one conversation, it's multiple conversations, over various time periods. They don't ever rule anything out, so if the consensus is they need to give them information of NRP, it will necessitate another conversation. They said it would be very awkward to change their process and not in line with what we've been doing for 30-40 years. A member suggested to consider the negative effect on donor family feelings if we limit the options for their loved ones to have their wish to donate after death fulfilled. An attendee said that asking for a level of informed consent is unnecessary. Another attendee pointed out that the transplant community is familiar with first person consent - Families have no say because their loved one agreed to donate, and families can't do anything about it. He explained that the donor family discussions can be painful and he would never want to have a discussion about NRP when a patient had decided to donate, and then the family aggressively disagrees. He believed that explaining the NRP procedure to donor families may make the community hesitant to donate. He believed the community should seek donor management and not NRP.
- An attendee was distressed by some of the assumptions in the paper, especially with the word "reanimation". In support of the paper an attendee commented that technical issues are important to think about, but would separate that from ethical and legal issues. They explained that the alternative to this is DCD, respect for this is important for patient autonomy. The fact that we are discussing reanimating the heart or reperfusing organs, we have to go back to the original intent that this patient was expected to pass. For that attendee, NRP is a legal issue not an ethical issue. It is important to go back and think about death means. For abdominal perfusion should not be an ethical concern at all nor a legal concern. I would urge all to think of this as a legal issue not ethical. An attendee commented that a key message is the donor wishes. TANRP and how we manage all of that. They suggested that the white paper have a separate section between TANRP vs. ANRP. They also recommended to be in control of the messaging and having trained personnel in media communication is important. Another attendee said that

this is more of a legal issue than an ethical issue. The alternative to NRP is DCD - which has the same result of the donor passing. There should be work done to clarify the definition of death to enable NRP. And that abdominal NRP should be whole heartedly endorsed.

- In opposition of NRP, an attendee pointed out that he has lost lungs to NRP, which he believed shouldn't be allowed to happen. He pointed out, that there are devices available where we can take the heart out of the body and put them into machines to see if they can work and we can still use the lungs. He opined, why are we all going after a method that is moving in a gray zone treating life and death, why don't we have to tie off the neck vessels if we're totally sure that the patient is dead. Then he explained that it is because of autoresuscitation which we've known about from DCD donors.
- A member suggested that the Ethics Committee re-evaluate NRP in light of recent publication regarding the absence of brain reperfusion in NRP. In opposition of the paper, an attendee commented that the paper's ethical analysis does not consider the donation process, will increase distrust in the community, and that donation opportunities will be lost. Another attendee commented that parts of the paper were more than a white paper and a policy recommendation.

## Updates

**Councillor Update**

- Comments: No comments.

**OPTN Patient Affairs Committee Update**

- Comments: No comments.

**OPTN Membership and Professional Standards Committee Update**

- Comments: Region 5 supported the MPSC's update. An attendee applauded the MPSC for digging into the definition of late declines to be more transparent as this is a necessary step. An attendee suggested that an additional metric should be how long an OPO takes to deliver data.

**Member Quality Update**

- Comments: An attendee suggested to include patient communication in their projects.

**OPTN Executive Committee Update**

- Comments: An attendee expressed support for continuous distribution in light of blood type O transplants.

**OPTN Strategic Planning Feedback Session**

- Comments: Several attendees believed the most important strategic goal is to increase transplants, successfully. Several attendees support a strategic goal of increasing the number of donors and available organs for use, including removing barriers that create disincentive to living and deceased donation and increased insurance coverage for living donors. Several attendees suggested to include equity. Additional suggestions for other strategic goals or

aspects of strategic goals: maximize organ utilization, access to transplants, standardized donor workup, healthcare disparities, increase allocation efficiency, recovery time, increase patient engagement through education and transparency, reduce non-use rate and emphasize appropriate use through allocation/distribution scheme.

**OPTN Policy Oversight Committee Update**

- Comments: No comments.