OPTN

Thank you to everyone who attended the Region 8 Winter 2024 meeting. Your participation is critical to the OPTN policy development process.

Regional meeting presentations and materials

Public comment closes March 19! Submit your comments

Continuous Distribution – tell us what you value!
The Heart Transplantation Committee is seeking feedback from the community to inform the development of heart continuous distribution allocation. The community is invited to participate in a prioritization exercise through March 19. You do not need to be a clinician, heart transplant professional or heart patient to participate. Click here to complete the exercise and provide your feedback.

The sentiment and comments will be shared with the sponsoring committees and posted to the OPTN website.

Non-Discussion Agenda

Update Post-Transplant Histocompatibility Data Collection

OPTN Histocompatibility Committee

- Sentiment: **2 strongly support, 9 support, 3 neutral/abstain, 3 oppose, 0 strongly oppose**
- Comments: Region 8 offered several suggestions for this proposal. In support of the proposal an attendee commented that it is an appropriate update that is consistent with current practice. Another opposed this proposal as currently written. A member agreed that laboratories should assess their virtual crossmatch practices as part of their internal quality assurance program. They explained this should be monitored by the laboratory in accordance with their testing and virtual crossmatch processes; it should not become a data mining platform or clinical competency assessment. They suggested that the proposal needs additional clarification regarding intent and may even be counterproductive to recent community advancements towards acceptance of virtual crossmatching by CMS. Several attendees pointed out the need for clear definitions for “virtual crossmatch”. They explained the community has not settled on a single definition for virtual crossmatch because of varying institutional needs. A member asked if a laboratory indicates that the virtual crossmatch and physical crossmatch are not concordant, will the OPTN consider this as a discrepancy requiring further explanation. It is expected that there will be some disagreement between virtual and physical crossmatches as they are not both tests measuring the same analytes. The member inquired if these "discrepancies" require justification of clinical consultations or testing practices. A member suggested that to nationally assess true correlations, not only must virtual crossmatches be performed in the same manner by laboratories, but physical crossmatching and antibody testing must also be standardized across the community. An attendee commented that to require OPTN data collection to correlate a virtual crossmatch (data-based analysis) with a physical T and B crossmatch (lymphocyte-based LDT) suggests that these two are not independent and that the results of each are linked. They commented that this contradicts the communities’ progress and CMS regarding crossmatching. (Notably, CMS has recognized the validity of virtual crossmatch as an independent crossmatch for use by clinical teams.)

Promote Efficiency of Lung Allocation

OPTN Lung Transplantation Committee

- Sentiment: **3 strongly support, 11 support, 3 neutral/abstain, 0 oppose, 0 strongly oppose**
- Comments: A member pointed out that filters worked well for kidney but will need data follow-up to determine if there are unintended consequences. An institution questioned the cost/benefit of adding the "history of anaphylaxis to peanut and/or tree nut" field since it is a rare event and has the potential to be marked positive in circumstances where risk of donor transmission of anaphylaxis would be low. They also questioned whether the surgeons want to know about previous thoracotomies, as well as sternotomies. They suggested expanding the set of potential criteria available to transplant programs.

Standardize Six Minute Walk for Lung Allocation

OPTN Lung Transplantation Committee

- Sentiment: **0 strongly support, 13 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose**
- Comments: No comments.

Clarifying Requirements for Pronouncement of DCD Donor Death

OPTN Organ Procurement Organization Committee

- Sentiment: **4 strongly support, 10 support, 1 neutral/abstain, 1 oppose, 0 strongly oppose**
- Comments: In support of this proposal, an attendee commented that as the transplant community utilizes more DCD options there is a need to clarify pronouncement of death. Another commented that this is well documented in literature.

Discussion Agenda

Standardize the Patient Safety Contact Notification Process and Duplicate Reporting

Ad Hoc Disease Transmission Advisory Committee

- Sentiment: **3 strongly support, 12 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose**
- Comments: Region 8 supported this proposal and offered suggestions. A member asked for clarity for what electronic notification means and did not support requiring UNET sign in (since reports may occur during non-business hours). An institution supported the proposal and requested the policy to clarify that only one of the PSC needs to be an employee of the transplant hospital/OPO, not that both need to be an employee. Several attendees support the requirement to list a secondary PSC and to review every 6 months for accuracy. Another attendee suggested an annual review. An attendee commented that OPOs should not be accountable when a transplant center does not acknowledge receipt within 24 hours. Another explained that attempting to verify safety contact information without requiring an immediate action or response is an unacceptable policy. The attendee suggested a more appropriate approach might be to employ a mass email/notification and add a requirement that all emergency contacts respond to the notification.

Concepts for Modifying Multi-Organ Policies

OPTN Ad Hoc Multi-Organ Transplantation Committee

- Comments: Region 8 provided constructive feedback for this concept paper. An attendee supported offering the second KDPI < 34 kidney to the isolated kidney list if the first is allocated

to a multi-organ or kidney-pancreas candidate. Another attendee commented that the Final Rule may favor the multi-organ candidate to maximize the number of organs transplanted, especially for kidney-pancreas since there are few pancreas-alone transplants. However, there would be kidney-alone recipients that are disadvantaged. The attendee suggested limiting allocating one kidney to the multi-organ candidate, and the other to the kidney-alone candidate in order to balance both interests. They suggested the committee do their best to make a transparent and clear policy, enforce it, study it for unintended consequences, then modify it, if needed. An attendee recommended that one kidney be allocated to a multi-organ candidate, then to a kidney-pancreas candidate, since multi-organ transplant is better for recipients at the time of the OPO allocation process. The attendee then explained that often a pancreas is declined in the operating room after the surgeon physically sees the pancreas. And if that occurs then the kidney should be allocated on the kidney-alone list. Another attendee said that the transplant hospital should not be allowed to rescind the acceptance because this could create more late turn downs. A member asked if it would be more appropriate for multiple organ offers to be run through the kidney-only list. A member pointed out that kidney-pancreas transplants should be considered a multi-organ transplant since there are two organs. An attendee inquired if there should be acknowledgment of the OPO making a second attempt. The member also suggested notifying both contacts at the same time.

Modify Effect of Acceptance

OPTN Ad Hoc Multi-Organ Transplantation Committee

- Sentiment: **5 strongly support, 11 support, 1 neutral/abstain, 0 oppose, 0 strongly oppose**
- Comments: Region 8 supported this proposal, believed the recommended priorities are reasonable, and provided the following commentary. An attendee suggested to be aware of the time factors associated with the acceptance policies. A member suggested considering allocating multi organs with single organs on the same list; which could help alleviate the issues with offering organs then retracting the offer due to multi organ offers. A member noted concern that this could create the possibility for misuse if an isolated organ is allocated outside of current policy. The member recommended modifying the policy language to explicitly constrain this to situations when the OPO has fully followed Policy 5.10 (and related organ specific policies) for prioritizing multi-organ allocation. In support of the proposal an institution explained they believe that once an organ is accepted, it's accepted and shouldn't be pulled back to fill a multi-organ transplant when another organ is turned down. They explained that waiting until the donor operating room is scheduled is too late and may lead to additional late turn downs. An attendee recommended the proposal offer an explicit definition of what "acceptance" means by clarifying provisional acceptance to placed. They explained that as they receive multiple offers from multiple OPOs, it does not seem that the words mean the same thing among different OPOs and programs. While an attendee acknowledged how difficult it is to do multi-organ allocation, and the difficulty lies in when the offers are rescinded. Another attendee explained that it is difficult to understand how acceptance is completed before procurement is finished. Lastly, a member suggested that multi-organ offers only be run through the kidney match.

OPTN Strategic Plan 2024-2027

OPTN Executive Committee

- Sentiment: **2 strongly support, 12 support, 3 neutral/abstain, 0 oppose, 0 strongly oppose**
- Comments: Region 8 supported the Strategic Plan and offered several suggestions. A member suggested a living donor goal and a patient outcome post-transplant goal. Another attendee commented that there should be objective and specific goals regarding living donation. The objectives of the goal should be improving the quantity and quality of data available to prospective living donors, the health & safety- both short-term and long-term, protection from financial and insurance-related impacts of their donations, and both long-term post donation follow-up of living donors. They explained that these are not stated metrics but hope patient and graft survival metrics will be included while implementing the goals stated in the Strategic Plan. While focusing on increasing acceptance rates, decreasing organ non-use and increasing transplants can be measured in real time. The member believed the Strategic Plan should do more to help improve the overall system. Another inquired as to what impact will the goals have on patient and graft survival both short and long term. They pointed out that honoring the donor's gift doesn't stop when that organs are transplanted, it continues through the entire life of the recipient. An institution asked to see a focus on maximizing the utilization of potentially usable organs, not just those for which OPOs have obtained consent. Another attendee suggested the OPTN incorporate SMART goals for the Strategic Plan.

Continuous Distribution of Hearts Request for Feedback

OPTN Heart Transplantation Committee

- Comments: An attendee requested that future updates include applicable statistics. A member institution said they need more clarity on the details and explained that predicting outcomes is difficult. They said the Lung Committee struggled with it as they incorporated post-transplant survival in CAS but felt that public comment supported the inclusion of longer-term outcomes in organ allocation schemes as a priority and this attribute (post-transplant survival) is consistent with NOTA and the Final Rule. The goal of this attribute is to have the highest number of patients surviving post-transplant at 1, 2 or 5 years. The member pointed out that SRTR does have post-transplant survival measures- for lung 1-year survivals are as predictive as 5 year survivals. While these predictions are difficult, they are a critical component of the CAS which is meant to consider the candidate wholistically. The presentation referenced that programmatic UNOS outcomes could be used as a surrogate for post-transplant survival attribute. While this has some validity, this approach would lead to disparate listing practices and thus inequitable organ access for patients at smaller programs. Smaller programs will be less willing/able to list patients while larger programs may be able to be more liberal. Moreover, this approach does not allow for a candidate to be considered wholistically, it applies to a program wide goal to individuals which could create inequity. Post transplant outcome is a necessary and important attribute to be included in all organ CAS. It is consistent with the principles of utility and equity and consistent with public comment priorities. Interim analysis can be utilized as well as prospective data collection to fine tune weights in organ specific cases. Imperfect data should not be used as a reason to not include post-transplant outcomes, one of strengths of CAS is that each attribute weight can be altered at regular intervals as we have seen in the lung implementation of CAS. An attendee expressed concern about the exclusion of a post-transplant

survival metric. The member suggested data collection efforts to leverage preexisting data in electronic health records for future development of post-transplant metrics. Another said this is a good effort and inquired about the prospects of getting an EPTS equivalent for transplant. A member suggested that pediatric candidates should be prioritized every time. And explained that from a donor family perspective there is no better way to honor the gift.

National Liver Review Board (NLRB) Updates Related to Transplant Oncology

OPTN Liver & Intestinal Organ Transplantation Committee

- Sentiment: **2 strongly support, 12 support, 3 neutral/abstain, 0 oppose, 0 strongly oppose**
- Comments: A member commented that this affects a small number of patients and is reasonable. An attendee pointed out that that for the metastatic cancer patients, the proposed MELD is too low, and these patients are unlikely to get viable liver offers.

Refit Kidney Donor Profile Index (KDPI) Without Race and Hepatitis C

OPTN Minority Affairs Committee

- Sentiment: **11 strongly support, 5 support, 1 neutral/abstain, 0 oppose, 0 strongly oppose**
- Comments: Region 8 supported this proposal. An attendee supported excluding the race based and HCV variables from the KDPI calculation to better assess the likelihood of graft failures. They inquired whether removing these variables will change the weighting of the remaining variables and accurately reflect risks. They also inquired about the plan to collect post-transplant survival data for kidneys when these variables are removed; and suggested that data collection should begin immediately upon policy approval. A member inquired if APOL1 testing would ever be available whether inside or outside the scope of KDPI. They suggested that Hep C status may still impact the decision to accept an organ but should not influence KDPI. And opined if there are other factors that should be added to improve KDPI predictive ability.

Updates

Councillor Update

- No comments or questions.

OPTN Patient Affairs Committee Update

- No comments or questions, but Region 8 greatly appreciated the speakers' presentation.

OPTN Membership and Professional Standards Committee Update

- Comments: A member explained that MPSC is trying increase the level of transparency with their activities, and asked the group to share any ideas and recommendations that would be helpful to members.

OPTN Executive Committee Update

- Comments: An attendee inquired how to engage HRSA and communicate the transplant communities' feelings about potential OPTN structural changes to HRSA.

Improving Organ Usage and Efficiency: Update from the Expeditious Task Force

- Comments: Region 8 appreciated the update from the Expeditious Task Force and both in-person and virtual attendees participated in a discussion, brainstorming, and feedback exercise.

As a result, an attendee inquired about addressing donor characteristics. It was mentioned that OPOs probably have a good idea about what an organ's characteristics are that will be successfully used. The individual stated that pre-clamp and post-clamp characteristics are very important. As part of the Policy Review discussion, an attendee suggested that the Organ Center not be involved with expedited placement of organs and that policy should be amended.

Another attendee discussed feedback about the potential to clarify specific codes: 830, 720, and 711 specifically.

HRSA Update

- Comments: An attendee supported the collection of referral data but explained they need to have cooperation of major EHRs in automating, and that more data collection means more resources needed. There were questions about the status and amount of funding. There was a specific question regarding whether HRSA considered getting ventilated patient death information directly from CMS. The attendee pointed out that OPOs have been criticized for 'self-reported data', and wanted to know how this is different. There was an inquiry about whether HRSA's RFP indicates having a new Board in place within six months, and whether that applied to the OPTN Committees as well. There was an inquiry on whether HRSA considered open source programming for the computer system.