OPTN

Thank you to everyone who attended the Region 4 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.

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 during the meeting, but attendees were able to submit comments with their sentiment. One attendee commented that the testing should not delay placement since this is such a rare occurrence.

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

- Comments: One attendee commented that the committee may want to consider right ventricular dysfunction in the face of a left ventricular assist device. Another attendee commented that the committee should learn from the lung continuous distribution implementation. They added that from an OPO perspective, the lung allocation does not factor in geography or donation after circulatory death donors (DCD) adequately, resulting in an unnecessary burden for OPOs and Transplant Centers. They went on to comment that while geography should not be the primary driver of allocation, it needs to considered more thoroughly. One attendee commented that medical urgency needs to be determined by the medical condition of the listed patient rather than the device chosen to support them. Utilizing more data elements that truly reflect severity of condition (estimated glomerular filtration rate (eGFR), creatinine, sodium, etc.) will be needed to balance out the device abuse that has become the new normal.

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

- Sentiment: **4 strongly support, 10 support, 6 neutral/abstain, 0 oppose, 0 strongly oppose**
- Comments: This was not discussed during the meeting, but attendees were able to submit comments with their sentiment. One attendee commented that this should be a first step as there is more data that should be collected. They added that future versions should include DCD methods of heart resuscitation, heart transport devices, solutions utilized and local versus transplant center procurement teams.

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

- Sentiment: **6 strongly support, 12 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose**
- Comments: This was not discussed during the meeting, but attendees were able to submit comments with their sentiment. One attendee commented that it is important to reduce donor transmitted diseases. Another attendee commented that the testing should remain optional unless seasonal and geographic endemic risk is high.

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

- Sentiment: **8 strongly support, 7 support, 4 neutral/abstain, 2 oppose, 0 strongly oppose**
- Comments: This was not discussed during the meeting, but attendees were able to submit comments with their sentiment. Two attendees commented that while the form was well intended, it delays the ability to get priority points and does not aid in the accuracy of the process.

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

- Sentiment: **3 strongly support, 9 support, 11 neutral/abstain, 0 oppose, 0 strongly oppose**
- Comments: This was not discussed during the meeting, but attendees were able to submit comments with their sentiment. One attendee commented that optimizing VCA recovery should not jeopardize recovery of other organs.

Update HLA Equivalency Tables 2023, *OPTN Histocompatibility Committee*

- Sentiment: **8 strongly support, 11 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose**
- Comments: This was not discussed during the meeting, but attendees were able to submit comments with their sentiment. One attendee commented that this update is a good step forward but was concerned that the high-resolution list is incomplete. They added that some alleles don't exist in the proposed table and are only identified at low resolution or serology. They went on to comment that using the International ImMunoGeneTics (IMGT) for the nomenclature/coding would have been strongly preferred. They were also concerned about the use of P groups as these are only a part of protein and although they predict T cell immunity, they are a poor proxy for antibody reactivity. Another attendee commented that the updates will enhance compatibility opportunities.

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

- Comments: This was not discussed during the meeting, but attendees were able to submit comments with their sentiment. One attendee commented that the community needs to better understand the impact of acuity circles and broader allocation before moving to continuous distribution.

Discussion Agenda

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

- Comments: One attendee commented that moving kidney and pancreas to continuous distribution needed to slow down so the committee can learn from lung continuous distribution in terms of what is working, what is not, and if there are any unintended consequences. They added that it seems as though each organ committee is working in a silo and not being informed by the practical experience of the community. They went on to comment that non-utilization of kidneys has increased in terms of percentage and real numbers since circles were implemented and we need to understand why before moving to continuous distribution of kidney and pancreas. Another attendee commented that they support investigating continuous distribution adding that the committee needs to prioritize pediatric candidates for kidney donor profile index (KDPI) under 35 donors. One attendee supported the efforts to improve kidney usage rates and decrease non utilization. They added that it will be important to decrease penalties for primary non-function to allow centers to take more kidneys without negative consequences. They also commented that there should be more communication between OPOs and centers to allow expedited offers for expanded criteria donor kidneys resulting in shorter cold ischemic times.

  During the meeting the attendees participated in group discussion sessions and provided feedback on one of three questions:
  - Dual Kidney Eligibility Requirements
    - One group of attendees commented about differences in the combination of using both donor criteria and offering the kidney as single first. They added that requiring allocation of a single kidney until a specific percentage of the match run has been offered to and declined is not the best idea and recommended using classifications and criteria within classifications to offer dual kidney as a better option when determining when to allocate kidneys as duel. They went on to comment that allocation of dual kidneys should be prioritized on the match to give more programs a chance to accept them.
    - Another group commented that the definition of when OPOs may begin to offer kidneys as duals should be based on donor criteria much like expedited allocation for: DCD, expanded criteria donors (ECD), high KDPI, cold ischemic time (CIT), age, serologies, biopsy. They were not supportive of using a percentage of the single kidney match run.
    - One group supported offering the kidneys first as single until a specific percentage of the match run had been offered to and declined but thought it should be up to the OPO to weigh in on when to pivot to offering the kidneys as duel.
    - One group supported offering the kidney as single first and if the OPO determines that the kidneys aren't being taken quickly then offer as open offer allowing centers to choose to take as single or dual.

        - A majority of the online attendees supported using a combination of donor criteria and offering single kidneys first.
    - Pancreas Medical Urgency clinical guidance
        - One group of attendees recommended medical urgency guidance for patients suffering from hyperglycemia unawareness particularly if they are diabetic and had hospitalizations for self-injury from hyper and hypo glycemia.
        - One group suggested using the criteria for islet transplant as a basis for criteria for medical urgency for pancreas.
        - There was mixed support for inclusion of an exception-based medical urgency attribute for pancreas with equal support for and against.
    - Mandatory Kidney Pancreas Shares Threshold
        - One group suggested using median waiting time for kidney candidates on list before giving priority to combined kidney/pancreas.
        - One group commented that their biggest concern is prolonged allocation time when trying to place combined kidney/pancreas.

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

- Sentiment: **3 strongly support, 11 support, 8 neutral/abstain, 0 oppose, 0 strongly oppose**
- Comments: Region 4 supported this proposal. One attendee commented that the Heart Committee has conducted themselves with rationale thought, expertise and community engagement providing rationale solutions. They added that the balloon pump issue is somewhat controversial depending on the transplant center. There will be situations where balloon pumps are necessary and they would not advocate for balloon pumps to go away, but rather look at data and adjust the status according to mortality rate. Another attendee agreed that the change was thoughtful and commented that there are appropriate utilizations after looking at data. They went on to suggest that one point to consider is inotropic levels prior to placement and that it makes sense for status 2, but there is a disconnect because there is no criteria in status 3 for balloon pump unless you don't meet status 2. Using mechanical circulatory support is preferrable. They added that if you have a lower level of inotropes and fail weaning from the device, you could go in with status 2. They added that maybe there should be criteria for an initial listing at status 3. Another member commented that there are patient scenarios where balloon pump is clinically appropriate over inotropes and that's the process for filling out data and explaining the request. They went on to comment that review boards did not effectively monitor this, which is why this is such an issue that now requires a policy change. They added that this isn't a balloon pump policy, this is a status 2 policy. One attendee commented that this could result in more exception requests. Another attendee commented that the committee should consider status 3 criteria for candidates who move to mechanical device support after failing a single inotrope. One attendee commented that each time the requirements in policy change for a specific device, drug, or patient location, there is an increase in utilization of that device or drug. They went on to question if this change would have any effect on the behavior. Another attendee commented that while this proposal will not address all the issues, it is a reasonable solution while continuous distribution is developed and could provide data that can be used for continuous distribution.

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

- Sentiment: **10 strongly support, 11 support, 3 neutral/abstain, 0 oppose, 0 strongly oppose**
- Comments: Region 4 supported the proposal. While there was not a lot of discussion during the meeting, attendees were able to submit comments in writing. One attendee commented that data is essential for tracking and system improvement. They added that collecting the data should not result in any punitive action but rather should inform improvement actions by members. Two attendees commented that it is critical that the MPSC report what types of events are occurring so OPOs and transplant centers can work to prevent such events in their systems. One added that this information should be reported back to the community every 3-6 months. Another attendee went on to comment that continuing to "black box" blinded, aggregated patterns and trends of patient safety events is a huge disservice to the community and sharing this information will likely be a component of reducing risk of repeated events in other agencies/geographies. Another attendee supported giving members 72 hours to report rather than 24 hours. One attendee questioned how compliance would be monitored. Another attendee commented that there needs to be more clarity about what types of events are expected to be reported so that the cause of the event can be analyzed. Another attendee recommended that living donors being registered on the waiting list within 2 years of their donation should only be required reporting if it is related to the donation and not if it is an unrelated reason (i.e. car accident, gunshot wound, etc.). One attendee commented that this will be an additional administrative burden.

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

- Sentiment: **4 strongly support, 10 support, 3 neutral/abstain, 3 oppose, 3 strongly oppose**
- Comments: Region 4 was split in their support of this proposal and had substantiative feedback for the committee. Several attendees agreed that the proposal was needed and would improve placement efficiency and organ utilization. They went on to comment that late turndowns sometimes result in the loss of an organ, which is unacceptable. There were several attendees who did not support the proposal due to concern about how this would impact pediatric candidates who are already limited in the organs they can accept due to size matching, organ suitability and travel distances. There were also several attendees who were concerned about how this policy would impact adult liver candidates with high MELD scores. This practice is needed for these high MELD candidates who have high mortality without a transplant and need to have access to appropriate quality organs. Another attendee added that highly sensitized candidates need to be allowed to have more than one offer acceptance. One attendee commented that late turndowns are often due to late biopsy results and if OPOs were able to get biopsy results earlier in the process, centers could make decisions earlier. One attendee supported limiting acceptances for liver candidates but commented that this should not apply to kidney acceptance since there is no perceived problem with late turn downs for kidneys.

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

- Comments: Several attendees supported this concept and collecting more comprehensive data on living donors. Those who supported collecting more data also commented that this needed to be done in a way to minimize burden to transplant programs through eliminating redundancy in other aspects of living donor data collection. Several attendees were concerned with requiring consent from the living donor (or potential living donor) adding that it would add burden and needed resources for the transplant programs. Other attendees supported a national registry for living donors to self-report their status. One added that providing quick access to respond to surveys or entering a survey online would provide the opportunity to capture more variables to access wellbeing. One attendee was very supportive of the data collection, adding that we do a disservice to living donors by not caring about their long-term outcomes. They added that lack of long term and more detailed living donor data means that clinicians have no facts to utilize to answer living donor candidates' questions about outcomes and lifestyle choices post-donation. They went on to comment that if we learn from those that consider donation, but do not donate, we may be more effective in recruiting living donors in the future. They added that we also need non-donor control comparisons. One attendee commented that this data collection seems like yet another unfunded research mandate for transplant centers who are already struggling with existing data burdens and proving actual care for their patients. They added that we need to focus on removing barriers to living donation rather than adding them.

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

- Sentiment: **7 strongly support, 7 support, 9 neutral/abstain, 1 oppose, 0 strongly oppose**
- Comments: Region 4 generally supported the white paper. One attendee commented that it seemed like the white paper is taking a certain position instead of analyzing the issue. They added that the issue of whether normothermic regional perfusion (NRP) violates dead donor rule or not hinges on the definition of death in each jurisdiction. They went on to comment that not every state has adopted the definition, and the committee needs to define circulation versus perfusion. Another attendee commented that they supported NRP to increase organ transplantation and agree that the ethics of the process needs to be evaluated as well as the analysis of the Dead Donor Rule. One attendee commented that they appreciated the committee taking on this complex and polarizing topic, however the paper's conclusion strongly highlights the need to create policy/standardized protocols surrounding NRP. They added that efforts should be made to expedite this work as the white paper may unintentionally place centers performing NRP at risk in the absence of policy/standardized protocols. Other attendees commented that this paper does not separate the issues of abdominal NRP (A-NRP) and thoracoabdominal NRP (ta-NRP) effectively and by not doing so, creates public perception rules that are not necessarily applicable to all protocols. One attendee added that the validity of the analysis may depend on whether the heart is involved. Another attendee added that an analysis of questions to be answered for each method, which again are very different, will be useful if the committee starts to make recommendations on practice. Several attendees commented that there is a need for education so that diverse communities of patients can understand the process. One attendee commented that if this white paper is endorsed it will be considered the OPTN position and they recommend additional work by the committee before

moving forward. Another attendee commented that while the conclusions in the paper are reasonable, the content of the paper needs clarification. They added that to state that NRP is recirculation is misleading as it is artificial without intent to revive the patient but rather to support the organs of the pronounced donor. They went on to comment that NRP is not providing blood flow to the person-that ended at declaration of death; it is providing flow to the donor. One attendee commented that this paper is a critically important contribution to the US and global donation and transplantation community that helps clarify the various ethical and clinical approaches to carefully evaluating the risks and benefits of evolving NRP organ recovery approaches. It is balanced, well researched and referenced and provides a pragmatic framework for organizations already performing this technique to review as well as for those considering. It is an extremely valuable and timely resource for all stakeholders, including the community at large, most importantly, potential donors and donor families.

Updates

Councillor Update

- Comments: None

OPTN Patient Affairs Committee Update

- Comments: None

OPTN Membership and Professional Standards Committee Update

- Comments: One attendee commented that this was a very good project with important pieces of feedback. They added that it is timelier than the Centers for Medicare and Medicaid Services (CMS) metrics for OPOs. They added that for process improvement the OPOs need to have data that is modelled and forecasted and more real time. They went on to comment that the CMS metrics are not risk adjusted so that the only group that does not get monitored by risk adjusted data is OPOs which is problematic for MPSC because they always use risk adjusted data and CMS is opposed to risk adjusted data. They added that mathematically it's impossible to get everyone to green. Another attendee commented that one thing that comes up a lot is the question of what aspect of OPO performance CMS is monitoring and is it the responsibility of the OPTN. One attendee commented that the concept of complementary is the right answer. Another attendee commented that one problem with metrics is that if they are not done well, they can be used as a punitive measure. This allows criticism because of how metrics are structured and evaluated. They added that we need to be mindful that national politicians expect the OPTN to be leaders in the community and should speak up if the CMS metrics are not the correct measurement. One attendee commented that considering geography and regional differences in public health perspective, using two years of COVID in the denominator is extremely difficult to justify without adjustment for mortality patterns.

Member Quality Update

- Comments:
    - No questions or comments

OPTN Executive Committee Update

- Comments:
    - No questions or comments

OPTN Strategic Planning Feedback Session

- During the meeting the attendees participated in a group discussion session and provided feedback on which of the ideas for strategic plan goals generated by the OPTN Board should be the prioritized, which was the highest priority, and if there were any key themes missing. The ideas from the OPTN Board were: to 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.
    - One group commented that they selected "public (rather than only patient) engagement through education" as the highest priority followed by "increase donors and available organs for use" and "maximizing the value of organs and increase post-transplant quality of life". They added that they chose "public engagement through education and transparency" as the highest priority because the community is under a public microscope and there is significant misinformation and issues reported that are out of context. They think that increasing engagement and trust will hopefully increase support and resources and in turn provide the ability to move things forward as a group. They also think this would help highlight current technology and utilization for ultimate increase in transplants. The group commented that two missing themes were increasing transplant longevity and a goal that allows transplant centers to embrace risk taking to encourage innovation and boundaries without penalization for those trying to move the needle. The group also commented that another theme could be regionalization of resources to improve efficiency and quality.
    - One group commented that they selected "increase patient engagement through education and transparency" as their highest priority. They commented that patient education needs to include more information about risk factors to help patients better understand the benefit of high-risk organs. They also selected "maximizing the value of organs and increasing post-transplant quality of life" and "improve allocation efficiency" as priority goals. They chose "maximizing value of organs and post-transplant survival" because if there is an increase in the number of organs without increasing maximizing the value, we have a push system with no pull. They added that they think the word "value" seems financial and that the word "benefit" would be more appropriate for what we are trying to achieve.
    - One group selected "Increase Transplants" as their highest priority commenting that increasing transplants allows for pull rather than push system as well as shift in broader acceptance practices based on supply and demand. This will be supported by efforts to maximize benefits of organs and consistent metrics across OPOs, transplant centers and insurance companies. The selected "Improve allocation efficiency" and "Increase patient engagement through education and transparency" as other ideas that should be prioritized.
    - One group recommended focusing the strategic goal around system efficiency and integration, commenting that if we had an efficient system, we would realize the other goals that are listed.

- One group chose “Increase donors and available organs for use” as the highest priority. They commented that ultimately maximizing the supply of organs and getting them to candidates as efficiently as possible in time, cost and logistics will result in more transplants.
- Those attending virtually prioritized “increasing donors and available organs for use” as the highest priority followed by “improving allocation efficiency” and “increasing transplants”. They noted that missing themes were prioritizing pediatric transplants and developing regulations that don’t discourage innovation.

OPTN Policy Oversight Committee Update

- Comments: None