OPTN Organ Procurement Organization Committee
Meeting Summary
September 19, 2023
Houston, Texas

PJ Geraghty, MBA, CPTC, Chair
Lori Markham, RN, MSN, CPTC, CCRN, Vice Chair

Introduction

The OPTN Organ Procurement Organization (OPO) Committee met in Houston, Texas and via Citrix GoToMeeting teleconference on 09/19/2023 to discuss the following agenda items:

1. Lung Continuous Distribution- Efficiency Workgroup Update
2. Pronouncement of DCD Donor Death
3. Ethical Analysis of Normothermic Regional Perfusion (Proposal)
4. MPSC- OPO Performance Monitoring Enhancement Workgroup
5. Update Guidance on Optimizing VCA Recovery (Proposal)
6. Potential Projects
7. Efficiency and Utilization in Kidney and Pancreas Continuous Distribution (Proposal)
8. Liver Continuous Distribution (Update)
9. Collect Donor CRRT, Dialysis, and ECMO Intervention Data (Proposal)
10. OPTN Task Force on Efficiency
11. Organ Offer Acceptance Limit Proposal

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

1. Lung Continuous Distribution- Efficiency Workgroup Update

The Committee received an update on the OPTN Lung Transplantation Committee's Continuous Distribution- Efficiency Workgroup.

Summary of discussion:

Decision: The Committee supports the work that is being done by the OPTN Lung Transplantation Committee, especially the workgroup, and provided feedback in support with suggested modifications.

Feedback included that mandatory offer filters should be explored for lung programs. There was general support for transplant programs using offer filters and acceptance criteria to screen off offers once these are available for lung transplant programs.

The OPO Committee voiced concern over the use of offer notification limits to improve efficiency. Members commented slowing down the rate of offers may not address concerns. They recommend solutions focused on reducing the volume of offers (e.g., filters) and suggested transplant programs hire more staff to handle the current offer volume. The OPO Committee members agreed OPOs who have not set any notification limits within the "local" range could be making more offers than necessary and the Workgroup could consider limiting further offers once an acceptance has been entered. The Workgroup could also consider allowing OPOs to set different limits by organ type.

The OPO Committee expressed concern over the current weight on placement efficiency under continuous distribution of lungs. Members stated there is not enough weight currently placed on this attribute and organs are currently traveling greater distances. Members emphasized that organs must be placed quickly due to travel times for recovery teams. The OPO Committee also highlighted challenges faced with multi-organ allocation. The OPTN Ad Hoc Multi Organ Committee is currently addressing this.

The Chair presented possible policy changes to lung donor testing. The OPO Committee members voiced concern about adding tests like bronchoscopies. They argued they may not be able to get bronchoscopies or chest X-rays from remote donor hospitals or even metropolitan hospitals that have reduced staff and/or have outsourced laboratory testing. They urged the Workgroup to consider additional challenges for the donation after circulatory death (DCD) population, e.g., additional consent needed for bronchoscopies. They emphasized it would be important to include a "not available" option to keep allocation moving.

The OPO Committee members expressed concern about timelines suggested by the Workgroup. They stated it would be challenging if OPTN policy requires arterial blood gases (ABGs) within 2 hours of offers. They added this would even be a challenge if required every 4 hours. They urged the Workgroup to consider requiring a frequency for ABG testing rather than a time period before the organ offer.

Next steps:

The Committee will continue to support the Workgroup.

2. Pronouncement of DCD Donor Death

The Committee discussed the *Pronouncement of DCD Donor Death* project, including a background about the project and the modifications to the current policy.

Summary of discussion:

Decision: The Committee did not make any decisions regarding this project.

The Vice Chair recommended there be consistency in language, specifically when using the terms "declaration" and "pronouncement", as they mean the same thing, but it would be helpful to keep the language uniform. A member noted that different occupations, such as police officers, are declaring death whereas doctors are pronouncing death, but this practice can vary by state statute. The Vice Chair voiced their concern that the phrase "actively serving in a role with the OPO or transplant program" will cause conflicts of interest, especially for OPOs. The Chair recognizes that there could be a perception of conflict of interest and is hopeful that this policy will mitigate that. They continued, saying that when there are two examinations of death, it is a checks and balances system, which can be beneficial. A member echoed the concerns of the Vice Chair.

A member recommended changing the term from "actively serving" to "concurrently serving", as they feel that just because the medical professional has consulted with the OPO or have worked for them in the past, it should not stop them from being able to declare death. A member questioned if it would be most useful to be specific about what the medical professional's role is rather than the organization they are associated with and if the specific duties of their role are detailed, it may help mitigate some of the conflict.

A member suggested shifting the language to become simpler and make it more donor-specific, rather than having language that is broad. A member emphasized that the intent is that it is not a transactional situation. A member voiced their support for keeping the language simple and taking out a few phrases that are adding unnecessary complexity to the policy. They continued, saying that OPOs will still have the ability to make their own organizational and internal policies to meet their needs. A member reminded the Committee that some transplant institutions have their own language about this process. A member said that it may also be in the transplant center agreement with OPOs so that OPOs are protected from conflicts of interest. A member advised inserting language within the medical directors agreements with OPOs about conflicts of interest statements, rather than putting it into policy.

Next steps:

The Committee will continue to draft language and make modifications to the proposed language.

3. Ethical Analysis of Normothermic Regional Perfusion (Proposal)

The Committee reviewed the OPTN Ethics Committee's *Ethical Analysis of Normothermic Regional Perfusion* (NRP) white paper.

Summary of discussion:

Decision: The Committee supported the white paper and gave the OPTN Ethics Committee considerations to incorporate when analyzing NRP.

A member recognized that NRP can increase transplants, and thus save lives, but question how much detail should be conveyed in conversations with donor families. The member expressed concern for limited consensus on how to discuss NRP with donor families and noted that standardization in this area would be critical for OPOs.

The Chair countered, expressing concern about prescribing specific talking points that OPOs must disclose to donor families, as each donor family varies on the information they want to hear. Donor coordinators must be prepared to address donor families who want to know everything regarding NRP and relevant processes as well as address donor families who may want as little detail about NRP as possible.

A member questioned how much of the discomfort surrounding disclosure comes from OPO staff perspectives or from the donor families. The member shared concerns about OPO staff transferring those concerns to donor families. The member noted that OPO staff should be mindful of this when working with donor families.

A member, who has experience with NRP, shared that they have not seen family issues, but they have noticed discomfort from donor hospital staff, which they believe will be the biggest challenge with NRP. They recommended a toolkit for donor hospital staff to help mitigate discomfort.

Next steps:

Feedback will be summarized, and the Committee will post an official comment on the *Ethical Considerations of Normothermic Regional Perfusion* white paper on the OPTN public comment website.

4. MPSC- OPO Performance Monitoring Enhancement Workgroup

The Committee received an update on the OPO Performance Monitoring Enhancement Workgroup from the Member and Professional Standards Committee (MPSC).

Summary of discussion:

Decision: The Committee supported the work and effort by the MPSC and voiced their concerns to be brought back to the Workgroup.

A member noted that they feel it is important that the data used in the workgroup is open and considered non-biased, which can be accomplished through this effort. The Vice Chair voiced their concern about self-reported data and cautions the Workgroup that this will not be an easy task.

A member noticed that there was nothing regarding donor registration, specifically on a state-level, which would be a beneficial metric to analyze. The Vice Chair mentioned their concern regarding the aggressive timeline, and stresses that the Workgroup should come up with meaningful information rather than producing less impactful work that would satisfy the timeline.

Next steps:

The Committee will continue to help support the OPO Performance Monitoring Enhancement Workgroup and provide feedback when necessary.

5. Update Guidance on Optimizing VCA Recovery (Proposal)

The Committee reviewed the OPTN Vascular Composite Allograft (VCA) Transplantation Committee's *Update Guidance on Optimizing VCA Recovery* proposal.

Summary of discussion:

Decision: The Committee provided feedback and input about OPO's and VCA transplants.

A member remarked that there are few programs equipped to perform VCA transplants, which poses a challenge to VCA allocation. They continued, saying that many OPOs don't have the opportunity to work with VCAs.

A member explained that there is limited general understanding of how VCA allocation works, and that it can be difficult to learn and approach VCA allocation.

One member remarked that it would be helpful to observe VCA allocation, to better understand how this process works. The member added that it would also be helpful to ensure OPOs have a general understanding of the requirements for VCA donation; the member noted that this information is not currently easily accessible.

One member shared that they rarely receive interest in VCA offers. The member explained that their teams have extensive training in VCA, but that there is limited opportunity for VCA transplant, and thus it is difficult for personnel to become proficient in the VCA field.

A member noted that there may be challenges in finding additional interest from OPOs for VCA transplants, particularly as Centers for Medicare and Medicaid Services (CMS) metrics for transplant programs do not consider VCA transplants.

Next steps:

Feedback will be summarized, and the Committee will post an official comment on the *Update Guidance on Optimizing VCA Recovery* proposal to the OPTN public comment website.

6. Potential Projects

The Committee discussed potential projects they would be interested in pursuing in the future. These included: DCD Project (Timing of Discussion), Transportation Arrangements, Corrugated Boxes.

Summary of discussion:

DCD (Timing of Discussion)

A member questioned if having preliminary discussions surrounding organ donation would be beneficial across all OPOs, as their OPO has these discussions and has seen an increase in preliminary donor assessments (PDAs). They recommended that all OPOs consider engaging in this practice. The Vice Chair believes that the Committee has an obligation to address the issue around the timing of discussion. The Chair said that with the increased number of OPOS using first-person authorization on DCDs makes this even more important because it helps prepare families members and make loved ones aware of an individual's desire to donate.

Transportation Arrangements

The Chair remarked that "responsible for determining" could mean "responsible for paying for", which is a big issue for OPOs. They continued, saying that clarifying language to determine cost for transportation would be helpful. The Vice Chair noted that this may not be an easy policy to navigate, especially since each OPO operates differently, which is part of the problem, thus developing consistency is essential.

Corrugated Boxes

The Vice Chair mentioned that this is not just an issue with the Joint Commission, but also with the Association of perioperative Registered Nurses (AORN), forcing operating room staff to leave boxes containing organs at the front desk, making it an inconvenience. They said that they put a clear plastic bag around the box, which is the temporary solution they have discovered. The Chair noted that they were unsure if a policy change is needed on this and maybe adding something to the policy allowing the equivalent, would suffice. They continued, saying that until the Committee receives a specific directive or question from the Joint Commission or AORN, they are hesitant to address this. The Vice Chair suggested taking "corrugated" out of the whole policy and saying the outer container needs to be able to have at least 200 pounds of burst strength.

Next steps:

The Committee will continue to investigate potential future projects.

7. Efficiency and Utilization in Kidney and Pancreas Continuous Distribution

The Committee reviewed the OPTN Kidney Transplantation Committee and OPTN Pancreas Transplantation Committee's *Efficiency and Utilization in Kidney and Pancreas Continuous Distribution* proposal.

Summary of discussion:

Decision: The Committee supported the proposal with suggestions.

A member commented that the system isn't set up successfully right now to have efficient dual kidney placement. This could be attributed to how the match run looks, how it is unclear who is and is not accepting dual kidneys, or who is managing dual kidney organ offers altogether. They emphasized that there are more issues to this process than what was presented in this proposal.

One member expressed concern that running a new match run would require the OPO to make new offers to the same candidates and programs, including those where the program has entered a provisional yes. Another member explained that the "carry over refusal" functionality and updates to

the “donor refusal” functionality will hopefully reduce this. The member also noted that the OPO would likely have received declines from those programs and candidates on the single kidney match run before beginning to allocate on the dual kidney match run.

A member shared that their OPO aggressively offers kidneys as dual once the donor meets certain criteria, including cold ischemic time considerations. The member noted that their OPO is transparent when making single kidney offers if the donor is more likely to meet that criterion. The member continued that dual allocation for hard-to-place kidneys needs to occur quickly, so that the organs can be rapidly transported to the programs that will transplant them so cold time can be minimized.

A member agreed and noted that their OPO uses a cold ischemic time trigger to begin dual allocation The member expressed support for OPO discretion in dual kidney allocation, particularly because each OPO’s practice currently vary based on local programs and considerations specific to the OPO. Another member shared that the timing of biopsy results is a potential trigger for dual kidney allocation at their OPO.

Next steps:

Feedback will be summarized, and the Committee will post an official comment on the *Efficiency and Utilization in Kidney and Pancreas Continuous Distribution* proposal to the OPTN public comment website.

8. Liver Continuous Distribution (Update)

The Committee reviewed the OPTN Liver and Intestinal Transplantation Committee’s *Liver Continuous Distribution* update.

Summary of discussion:

Decision: The Committee supported the update and provided insight on how to make improvements to continuous distribution.

One member recommended modeling or data analysis to understand how many centers would be qualified to receive medically complex donors.

A member noted they like the idea of using greater than or equal to 30% hepatic steatosis when categorizing “hard to place” livers and allocating them more quickly because they tend to get the liver biopsy results late. The member recommended that a new match be run once a liver biopsy has been performed to prioritize centers that accept highly medically complex livers. A member suggested that the timing for when OPOs can place their livers expeditiously be modified to allow expedited allocation once they receive a biopsy result.

A member pointed out that pre-recovery liver biopsy is not always an option, particularly because more than 40 percent of donors are DCD. The member suggested using non-invasive liver elastography to perform assessment of livers. A member shared that their program found limited correlation between non-invasive elastography and in-OR liver assessments, and therefore did not recommend using non-invasive elastography alone.

A member questioned, since the Liver Committee is looking at operational efficiencies, if there has been any more discussion surrounding the multiple acceptance proposal.

A member mentioned they think it will be interesting to see the effect of the organ offer acceptance performance metric, which is part of the OPTN Membership and Professional Standards Committee (MPSC) review as of July 2023, especially how it might push performance. They are concerned with past

performance evaluation, as medical team members impacting the feedback may leave the program, which could prevent a program from getting back on track.

A member is concerned with having one candidate listed at two centers, as this could make programming more challenging.

A member noted that allocating DCDs locally has been beneficial for them. A member said it's the expense of traveling for a potential DCD donor that might progress to become an actual donor. Therefore, having the ability to prioritize local centers that are willing to put the resources forward makes a difference in utilization, especially with the truncated timeline for DCD donors.

A member said that smaller liver transplant programs are less likely to take marginal organs compared to larger programs due to the potential impact on their program if there is a poor outcome. They worry that this will allow larger programs to continue to grow, whereas smaller centers will not have the same opportunities. The member voiced that they believe that access to transplant comes down to insurance and that uninsured candidates are disenfranchised. Insurance drives what the match run looks like and what the match run looks like drives how aggressive a center is. They continued, saying allocation out of sequence is problematic, but not as problematic as organ non-use, which should be at the forefront of the Liver Committee's focus. They recognized that OPOs are judged by organ placement and transplant programs are judged by outcomes, which makes a huge difference.

A member raised concern about the point-system, especially since they predict the big programs getting bigger, and the small programs getting smaller. The smaller/newer programs may not have the opportunities to accept medically complex livers, thus never getting points in that category. They recommended that the Committee consider that when evaluating the number of points for that attribute, as well as how frequently centers are evaluated with that.

<u>Next steps:</u>

Feedback will be summarized, and the Committee will post an official comment on the *Liver Continuous Distribution* update to the OPTN public comment website.

9. Collect Donor Continuous Renal Replacement Therapy (CRRT), Dialysis, and Extracorporeal Membrane Oxygenation (ECMO) Intervention Data (Proposal)

The Committee reviewed the OPTN Operations and Safety Committee's (OSC) *Collect Donor CRRT, Dialysis, and ECMO Intervention Data* proposal.

<u>Summary of discussion:</u>

Decision: The Committee supported the proposal and gave some suggestions.

A member asked if this information would be used in real time for offer evaluation. The member remarked that date and time fields should remain separate, and recommended alignment with how this information is collected in donor records.

One member asked if the panel would allow more than one therapy to be input into the donor record in the OPTN Donor Data and Matching System. The member asked if nitric oxide would be considered an inhaled therapy.

A member wanted to clarify that the OPTN Computer System wasn't being designed to be the only source of truth for donor clinical information instead of electronic medical records. It was confirmed that the intention was for the OPTN Computer System to continue to provide donor clinical information

and a matching system, but that the OPO electronic medical record system would still be used by OPOs, and the two systems would communicate with each other.

One member expressed support for this proposal, noting benefits to standardization and consistency in how this information is documented and shared.

A member recommended that all support therapies be documented from all hospitals (if they were transferred) and suggested the terminology “this event” rather than “this admission”.

A member advised including the hospital admission where the donor’s death was officially pronounced.

One member recommended specific consideration for how transplant programs see and access this data, particularly as transplant program users are the ones who need this information for offer evaluation.

A member suggested changing the name to say “Meds, Fluids, and Interventions” rather than just “Meds and Fluids”.

Next steps:

Feedback will be summarized, and the Committee will post an official comment on the *Collect Donor CRRT, Dialysis, and ECMO Intervention Data* proposal to the OPTN public comment website.

10. OPTN Task Force on Efficiency

The Committee received an update on the OPTN Task Force on Efficiency.

Summary of discussion:

Decision: The Committee did not make any decisions regarding the Task Force on Efficiency.

A member asked how the Task Force will be measuring success. A member suggested that the Task Force look at the reason for organ non-use and make adjustments to the allocation system, whether that be the current system or continuous distribution.

Next steps:

The Committee will continue to receive updates about the Task Force on Efficiency at upcoming meetings.

11. Organ Offer Acceptance Limit Proposal

The Committee reviewed public comment feedback on the *Modifying Organ Offer Acceptance Limit* proposal and identified the next steps.

Summary of discussion:

Decision: The Committee will keep the language of the proposal as it was proposed in public comment.

A member suggested creating a carveout specifically for DCDs, as an unintended consequence of the proposal is that transplant centers will decline DCD livers, and DCD liver utilization may decrease as a result. A member voiced their support for increased communication but does not think that is the sole solution to the problem at hand.

The Chair expressed their desire to keep the policy language the same as when the Committee proposed it. They continued, saying that having exceptions will still disadvantage higher status candidates who were on the match run. The Chair emphasized that having a timeframe mandate would be impossible to enforce, as operating room times get altered for a variety of reasons that are out of the OPOs and transplant centers control. A member agreed, saying that sometimes personnel issues can also be a factor in timing and that time is not measurable and constantly changing, thus making a timing mandate impossible to implement. The Chair brought up that none of the other options address the impact that late declines due to multiple organ offer acceptances has on other organ transplant teams such as heart, lung, and kidney. They elaborated, saying that multiple acceptances create havoc in the transplant system.

A member suggested that exceptions for Status 1A and 1B for liver candidates be implemented, as these candidates are in massive hepatic failure and are going to die. A member pointed out that the Status 1A and 1B candidates, as well as the high MELD candidates, are the ones that are causing the problem, as they are the ones receiving offers. They continued, saying that if this was explained in simple terms, it would make sense to more individuals, as many transplant surgeons do not pay attention to the problem and explaining it would help alleviate the issue.

A member voiced their opposition to the proposal as it is currently written, urging the Committee to take into account the opposition heard during public comment. They elaborated, saying they personally believe in this policy but believes the feedback heard during public comment must be paid attention to in order to be successful. A member agreed, questioning the Committee's opposition to having an exception. A member said the biggest issue is allocation and by allowing multiple organ offer acceptances, it is prohibiting sick patients from getting appropriate and essential organs. They proceeded, saying that allocating organs out of sequence is the wrong thing to do and it is something that can be easily preventable.

The Vice Chair mentioned that even if an exception was put into place for DCD donors, it would still pose a barrier for donation after brain death (DBD) donors, making it challenging from an operational standpoint. They added that if the proposal passes, the Committee will commit to closely monitor post-implementation very closely. A member noted that they agree with the public comment, but the answer is better communication, which hopefully will be a result of this policy. A member commented that a challenge with giving exceptions is that there will more requests for them, which would be an unintended outcome if the Committee decided to allow exceptions for Status 1A and 1B candidates.

Next steps:

The Committee will formally vote on the language at the October 19th meeting.

Upcoming Meeting

- October 19, 2023 @ 1 PM ET (teleconference)
- November 9, 2023 @ 1PM ET (teleconference)

Attendance

- **Committee Members**
  - PJ Geraghty
  - Lori Markham
  - Kurt Shutterly
  - Clinton Hostetler
  - Daniel DiSante
  - Donna Smith
  - Doug Butler
  - Erin Halpin
  - Greg Veenendaal
  - Lee Nolen
  - Micah Davis
  - Samantha Endicott
  - Sharon Sawczak
  - Stephen Gray
  - Theresa Daly
  - Jim Sharrock, Visiting Board Member
  - Valerie Chipman (Virtual)
  - Leslie McCloy (Virtual)
  - Judy Storfjell (Virtual)
  - Kevin Koomalsingh (Virtual)
- **HRSA Representatives**
  - Adriana Martinez
  - Jim Bowman
  - Marilyn Levi
  - Mesmin Germain
- **SRTR Staff**
  - Jon Miller
  - Katherine Audette
  - Nick Wood
- **UNOS Staff**
  - Robert Hunter
  - Kayla Balfour
  - Katrina Gauntt
  - Cole Fox
  - Joann White
  - Kaitlin Swanner
  - Kayla Temple
  - Kelley Poff
  - Kieran McMahon
  - Krissy Laurie
  - Laura Schmitt
  - Lauren Mauk
  - Lindsay Larkin
  - Matt Cafarella
  - Meghan McDermott

- Ross Walton
- Sharon Shepherd
- Stryker-Ann Vosteen
- Susan Tlusty
- Taylor Livelli

- **Other Attendees**
  - Andrew Flescher
  - Angel Carroll
  - Arpita Basu
  - Kim Koontz
  - Marie Budev
  - Sandra Amaral
  - Scott Biggins