OPTN Transplant Administrators Committee
Meeting Summary
February 1, 2023
Chicago, IL

Susan Zylicz, MHA, BSN, CCTC, Chair
Jason Huff, MSN, RN, FNKF, Vice Chair

Introduction

The Transplant Administrators Committee (the Committee) met in Chicago, IL on 02/01/2023 to discuss the following agenda items:

1. Welcome & Ice Breaker
2. Fiscal Impact Group Discussion
3. OPTN Member Information Security Policy Enhancements
4. Policy Oversight Committee Update
5. Optimizing Usage of Offer Filters
6. Ethical Evaluation of Multiple Listing (White Paper)
7. Continuous Distribution of Livers and Intestines (Request for Feedback)
8. Expand Required Simultaneous Liver-Kidney Allocation
9. Identify Priority Shares in Kidney Multi Organ Allocation (Concept Paper)
10. Continuous Distribution of Kidney and Pancreata (Committee Update)
11. Post Cross-Clamp Test Results Project
12. Open Discussion

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

1. Welcome and Icebreaker

The Committee Chair welcomed the Committee and encouraged a round of ice breakers to facilitate conversation and make introductions.

2. Fiscal Impact Group Discussion

The Committee considered improvement for the FIG process and how to create a balanced FIG group for these impact estimates.

Summary of discussion:

Committee members discussed how to pick new members for the FIG as some roll off this summer from the Committee. A member suggested nominating someone as the Chair of FIG who can act as a liaison or representative for the group when in communication with OPTN staff. One member recommended simplifying the questions asked on the survey, including grouping certain questions together, or having individuals rank items on a high/medium/low scale. The question was raised whether other committees understand the variability of impact by center, as each center might have a different way of data collection or policy enforcement. Such scenarios would complicate assigning a comprehensive fiscal impact to a proposal. Another member wanted to know what is done with these surveys and assessments after the fact, how they are used, as that would inform changes that could be made.

Next steps:

The Committee agreed to continue the conversation of revision to both the survey and how it could best be utilized at future Committee meetings.

3. OPTN Member Information Security Policy Enhancements

A member of the Network Operations Oversight Committee (NOOC) presented the proposal to Establish Member System Access, Security Framework, and Incident Management and Reporting Requirements.

Summary of discussion:

A member asked how many system issues have occurred where the threat came from a member institution. The NOOC Chair responded that there have been several ransomware and other similar attacks and the OPTN Contractor did work with those institutions to resolve the issues. However, he noted that the OPTN was not notified of these vulnerabilities until well after the fact and this put sensitive information at risk.

A member expressed concern about the annual certification process. She added that most hospitals have secure systems because healthcare systems are often targeted. She did not believe that an audit by the OPTN will identify weaknesses in security and end up being a burden to members without a true benefit.

Another member expressed a similar concern and noted that cybersecurity is taken seriously, and her institution employs an entire cybersecurity team. She added that creating audits and attestation requirements is an overreach when there have only been a few instances of vulnerability identified. The NOOC Chair responded that the goal is to have individuals who will work directly with the OPTN Contractor and take the proposed security framework back to each institutions IT personnel for review. The goal is not to revise all the IT security systems, but to know how transplant is involved and interacts with your existing security frameworks. He added that some IT security systems are robust while others, particularly smaller institutions, that might need some additional work to meet the proposed requirements.

A member agreed and commented that there are differences for various systems as well. She asked what sort of Health Insurance Portability and Accountability Act (HIPAA) requirements are different than the general security requirements for healthcare systems. The NOOC Chair responded that security frameworks can be different if they meet the minimum requirements once these are identified.

A member agreed with designating a security contact and commented that smaller organizations will be the ones most impacted by these requirements. She asked if there would be an “opt out” option for those larger institutions that already have robust security frameworks in place. The NOOC Chair responded that the issue with allowing some programs to opt out is that IT and cybersecurity are always evolving as the "bad guys" get more sophisticated. He added that the industry standard frameworks adapt and change as well. He noted that the annual attestations are going to help the OPTN Contractor better understand the member organization’s systems and where potential problems can be identified. Lastly, he noted that larger institutions are typically the target of cyber-attacks so they would not be exempt from these requirements.

A member noted that it might be beneficial to align OPTN requirements with existing US Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) requirements for cybersecurity so there is not duplication or conflict with other requirements. The NOOC Chair responded that there are frameworks that the OPTN Contractor has already met and added that CMS does not currently have the framework requirements.

A member asked if the OPTN Contractor is meeting the requirements that are being asked of members. The NOOC Chair responded that the OPTN Contractor undergoes periodic external audits to ensure their security framework is up to date.

A member expressed concern about access to the network being suspended in the case of a breach. He asked if there have been discussions about how a transplant center can provide services to their patients if this happens. The NOOC Chair responded that in the case of a cyber-attack, an institution should notify the OPTN Contractor so that arrangements can be made to still provide access to the necessary systems to mitigate the impact on transplant services. He added that the goal is to be collaborative to protect our systems while maintaining the ability to provide transplant services.

A member asked if the audits would be similar to the typical UNOS site visits or would it be a virtual audit. The NOOC Chair responded that it would be a different process since site surveys are conducted every three years. Additionally, the focus of the audits is to ensure systems are secure and improve collaboration that include clarity and transparency about the requirements.

Next steps:

Committee staff and leadership will draft a public comment response from the Committee based on the feedback given in the meeting. This response will be posted on the OPTN website.

4. Policy Oversight Committee Update

The Vice Chair presented updates from the Policy Oversight Committee. The presentation included the POC's role in the policy development process, including the following:

- New project review
- Pre-public comment review
- Policy priorities
- Benefit scoring
- Post-implementation monitoring

Summary of discussion:

The Committee did not have questions at this time and felt sufficiently updated on the POC progress.

5. Optimizing Usage of Offer Filters

The Committee received a public comment presentation on the proposal on *Optimizing Usage of Kidney Offer Filters* from the Operations and Safety Committee (OSC).

Summary of discussion:

A member complimented the Operations and Safety Committee for taking the feedback provided during the previous public comment period and identifying candidates that should be excluded from the offer filters. She expressed concern about the 90-day period to re-evaluate the offer filters.

A member from a pediatric program expressed concern about the impact on pediatric patients. For example, if a pediatric patient turns 18, would the offer filters be applied to them. He also recommended when a transplant program declines an offer for a patient having a "smart feature" that auto applies filters for that patient moving forward.

A member expressed concern that acceptance behavior can be based on the type of offers a transplant program is receiving, such as one with increased cold ischemic time. The Operations and Safety Committee Vice-Chair responded that the model allows programs to make modifications as needed.

A member asked how transplant centers can ensure that the application of the computer model is clinically relevant and based on what offers are being accepted. He added that nobody wants to miss out on offers if the system is selecting offer filters based on behavior. Lastly, he asked if the community really understands how offer filters work.

A member commented that offer filters could be an unnecessary burden for some centers. He added that it probably won't change center practice as some surgeons have been practicing for 20 years at some programs.

A member noted that her center uses offer filters and has found it beneficial. Her transplant center accepts more kidneys because staff has less "offer fatigue" and able to focus on offers that will actually lead to an acceptance. Another member added that the nurses can have more say in conversations with surgeons around which organs to accept based on the data from this system.

A member noted that offer acceptances are most likely different in New York City than Colorado. Another member added that some centers are never accepting organs from certain donors, and offer filters force important and challenging conversations with surgical and medical teams.

A member expressed concern about requiring transplant programs to review their offer filters every 90 days, even if it's simply turning them off. He recommended providing the ability to check a box stating they will do their own filtering as some centers know how to work the process. Another member commented that transplant centers that "opt out" should be re-evaluated.

A member suggested creating filters based on an organ offer acceptance ratio. Another member noted that creating default offer filters is not the right approach to increase adoption, but instead suggested creating a system that is smarter and more usable.

A member asked the group how to get transplant centers to adopt offer filters in order to improve the allocation system. She added that people avoid progress until it becomes mandatory. Another member suggested reviewing organ offer acceptance data and identifying those centers who fall in the bottom half of the country. He stated that those centers are the ones that should be forced to use offer filters.

A member suggested that 90 days may not be enough time to establish a pattern of acceptance behavior.

A member asked how transplant centers would be notified that offer filters will be turned on or modified. She added that it might depend on who gets the notification and when they are turned on, suggesting that weekends and holidays be avoided.

A member recommended letting transplant centers know what their current filters are and what the upcoming changes will be. She suggested giving transplant programs the option to accept or decline the new filters.

A member questioned if there is selection bias with later sequence numbers. Another member opined that offer filters might improve acceptance rates, although her surgeons have been reluctant to use filters due to lack of trust in the system.

A member suggested reviewing the correlation between a transplant center's offer acceptance practices and waitlist mortality.

6. Ethical Evaluation of Multiple Listing (White Paper)

The Committee received a public comment presentation on the white paper *Ethical Evaluation of Multiple Listing* from the Ethics Committee.

Summary of Discussion:

A member noted that insurance companies really restrict some patients from multi-listing. Another member asked if it was fair to tell a patient they can't list at more than one center. While it is true that Medicare and Medicaid might prevent some patients from listing outside their state, prohibiting the practice would limit those who have done the research and work to multi-list.

A member noted that it comes down to equity. Some patients can multi-list while other cannot, whether that is due to insurance or financial issues. Another member added that some private insurers require their patients go to a "center of excellence" and only certain centers are on that list.

A member suggested getting input from the Patient Affairs Committee. Another member requested information on insurance status for those individuals who are multi-listed. The Ethics Committee representative responded that the committee did review that information. Those who multiple list were more likely to have private insurance or self-pay. Additionally, there were more patients with college degrees who were multi-listed. He added that education does have an impact on health literacy and the ability to navigate the nuances and difficulties of the system.

A member asked what percentage of patients were multiple listed. The Ethics Committee member responded that 5% (6,000) of patients on the wait list were multi-listed.

A member questioned how many patients are transplanted at their "home center" versus at the second center where they are listed. Another member noted that a lot of patients in her area multi-list because there are three transplant centers within a metropolitan area.

7. Continuous Distribution of Livers and Intestines (Request for Feedback)

The Committee received a public comment presentation on the request for feedback on *Update on Continuous Distribution of Livers and Intestines* from the Liver and Intestinal Transplantation Committee.

Summary of discussion:

A member stated that the transplant community is looking forward to seeing progress on liver continuous distribution and encouraged other committee members to participate in the liver prioritization exercises.

A member asked if the liver group has been communicating with the lung group to learn from their experiences with developing and implementing continuous distribution. Staff responded that committee leadership and internal support staff for the various committees, including the Pancreas and Kidney Committees, are communicating on a regular basis to learn from each other.

A member recommended developing a patient pamphlet similar to what was done in 2005-2006 for the previous lung distribution changes. She added that it was helpful to provide patients with information about the allocation changes and how the new system might impact them. Another member added that both a paper and online version could be beneficial for some patients.

Staff reminded committee members about the liver prioritization exercise that is currently available on the OPTN website.

8. Expand Required Simultaneous Liver-Kidney Allocation

The Committee received a public comment presentation on the proposal to *Expand Required Simultaneous Liver-Kidney Allocation* from the Ad Hoc Multi-Organ Transplantation (MOT) Committee.

Summary of discussion:

A member asked for clarification about the sequencing for simultaneous liver-kidney allocation. The MOT Committee Chair responded that currently the OPO must follow the match run and there might be

a liver alone candidate. She added that this proposal is related to the concept paper that she will present next to the committee.

A member expressed concern about the additional travel distance being required with this change. The MOT Committee Chair responded that it will increase travel in certain regions, but the data also showed there were some inequities in access for those regions which led the committee to propose increasing the distance from 250 nautical miles (NM) to 500 NM.

9. Identify Priority Shares in Kidney Multi Organ Allocation (Concept Paper)

The Committee received a public comment presentation on the concept paper to *Identify Priority Shares in Kidney Multi-Organ Allocation* from the Ad Hoc Multi-Organ Transplantation (MOT) Committee.

Summary of discussion:

A member recommended that pediatrics should get kidney priority before multi-organ candidates so they are not disadvantaged by MOT allocation. The MOT Committee Chair agreed that in general pediatric patients should get priority for a kidney alone over MOT, however input from the Liver Committee suggested that it cannot be done for every situation so some flexibility needs to be built into the system.

Members supported the idea of balancing single kidney candidates with MOT candidates with certain criteria or restrictions. A member expressed support for the upcoming implementation of the safety net for heart-kidney and lung-kidney allocation. She further added that consistency across all OPOs is necessary when it comes to allocating the kidneys to kidney alone versus MOT.

A member supported the idea of offering one kidney to the MOT candidate and the second kidney to a kidney-alone candidate. Another member added that the "binding offer" issue needs to be addressed since all match runs are not done simultaneously. Another member added that if an OPO is kidney only focused, they might run the kidney first every time and have that binding offer already set.

A member suggested that the order in which match runs are made needs to be evaluated because it impacts MOT allocation. The MOT Committee Chair responded that it is on the list of projects for the committee to address in the future.

A member opined that he found it hard to understand that kidney-pancreas and heart-kidney have the same weight. Another member added that some surgeons at her transplant center believe that if you don't transplant the pancreas that the diabetes will continue and lead to poor outcomes.

Lastly, the MOT Committee Chair noted that the committee would like to put all MOT policies into one policy. A member responded that it would be helpful to members to do that.

10. Continuous Distribution of Kidney and Pancreata (Committee Update)

The Committee received a public comment presentation on the *Continuous Distribution of Kidneys and Pancreata Committee Update* from the Kidney Transplantation Committee and Pancreas Transplantation Committee.

Summary of discussion:

A member asked if the OPTN reviews how often a transplant center accepts a kidney-pancreas offer but then states the pancreas is not transplantable and keeps the kidney. The Pancreas Committee member noted that in current policy, if a receiving center decides after the fact that they don't want one of the organs, then the organ should be reallocated if possible. Another member added that it probably happens more for pancreas post procurement than any other organ.

A member commented that her transplant center accepts a lot of DCD pancreases and they split the costs or the charter fees with the OPO or get a waiver. The Pancreas Committee member stated that he would take this feedback to the committee for consideration.

11. Post Cross-Clamp Test Results Project

Information Technology (IT) staff presented an overview of this enhancement project that will allow organ procurement organizations (OPOs) to electronically notify transplant programs about culture results received following cross clamp or transplant.

Summary of Discussion:

A member commented that her center gets notified a lot for negative culture results and the notifications should be focused on positive results that might require prompt action by the transplant center. Another member added that there is inconsistent practice on when the results are reported as her team might get calls at 2:00 am for normal results.

IT staff noted that this project will not replace the reporting requirements in the patient safety portal.

A member asked if this notification will be done through email and text notification. IT staff responded that initially it will be done through both texts and emails.

A member asked if members will be provided with the match ID number with the notifications. IT staff responded that it will be provided.

A member asked if the notification would indicate if the result is negative or positive, because a negative result does not require immediate action by the transplant center. She added if the notification does not mention the result, it could be disruptive to staff who must log into the system so view the report.

A member expressed confusion about when the OPO would be required to notify the transplant center. Staff responded that the system would provide information to the OPO about whether the patient was removed from the waitlist or if there is an acceptance of the offer.

A member asked which staff members will receive the notification. IT staff responded that the patient safety person, primary on-call, and back-up on-call person will receive the notification. Staff added that if it's a positive result, the on-call person should be notified as soon as possible.

A member stated that she will need to discuss this with her patient safety contact since she does not receive these notifications. IT staff noted there will be focus groups formed over the next few months to solicit additional input from the end users.

12. Open Discussion

Staff provided committee members to discuss any topic or area of concern.

Summary of discussion:

Discussion eGFR

A member asked other committee members if they have started sending letters out yet. If so, do committee members have suggestions for improvement or developed any talking points in case of questions from patients. Additionally, she asked if members plan to provide the letters to black patients at the time of evaluation.

A member mentioned that they only have one patient affected, and whether it would be possible to simply put two letters together to ease burden on employees. Staff informed the Committee that more sample letters and talking points were being reviewed by HRSA and would be available soon.

A member noted that the letter states to call ones' transplant center and not UNOS with questions but felt that centers don't have enough information either. Staff acknowledged that FAQs would be made available at all levels, patient and center, and that any feedback on the FAQs or questions the centers might be receiving would be appreciated.

Another member asked what level of patient participation and responsibility could be expected during this process, as there might be patients affected who have moved and not notified their center, be inactive, etc. and yet these patients might not have the knowhow to dig into their own medical history. They mentioned concerns of furthering disparities in these instances but wanted to also remain conscientious of the burden on centers.

One member asked whether there was a deadline for notifying patients about the policy change, which staff affirmed there is no deadline for that portion, as centers have differing numbers of patients to notify. The OPTN is monitoring which centers have submitted thus far and is also receiving feedback related to best practices. The member also wanted to know whether the UNOS site survey would include questions pertaining to patient notification. Staff confirmed that it would not be on the site survey, but that centers would be required to submit their attestations to having notified patients about the new eGFR policy and whether it affects them by January 3, 2024. Staff also confirmed that inactive patients must also be notified.

A member asked if they could be provided with consistent talking points when speaking with patients, as many might not know it is a national policy. Another member noted that they included this information in the letter they've sent out to patients, to inform them that it is a nationally implemented policy and not just center specific.

Extra Vessel Storage

A member brought up a concern relating to policy about extra vessel storage. They had sent an open letter to the MPSC, requesting a re-review of Policy 16.6 which dictates policy regarding extra vessel usage and storage. The member stated that they never received a response to their letter, which had been submitted the previous summer/fall, and wanted to know what else could be done to get feedback regarding this issue. This member also clarified that they had been informed the letter would be reviewed by multiple committees but did not hear anything further.

The Chair concurred that this is an important issue to follow up on, although they might not be a policy development committee, they could bring more light to this and discern where the letter might have ended up. Another member questioned why the policy stated vessels had to be destroyed at 14 days post transplant, as according to their research, there is nothing to support this timeline. Staff acknowledged that there must have been a breakdown in the communication and stated they would follow up shortly with more information for the Committee and the member in question.

A member suggested adding this issue to a future meeting agenda so that they could discuss it more in length, to which the Committee agreed. The Committee also felt that this might be an opportunity to review policy and ensure that clinical data supports the existing policy or make changes if that is not the case.

Upcoming Meeting

- March 22, 2023 (Teleconference)

Attendance

- **Committee Members**
  - Susan Zylicz
  - Nancy Metzler
  - Rachel Detwiler
  - John Gutowski
  - Joshua Gossett
  - Michelle James
  - Denise Neal
  - Erica Seasor
  - Kay Shields Ragan
  - Christopher Wood
  - Stephanie Johnson
  - Brian Roe (Virtual)
  - Jason Huff (Virtual)
  - Megan Fairbank (Virtual)
  - Melissa Roberts (Virtual)
  - Sarah Madgwick (Virtual)
- **HRSA Representatives**
  - Megan Hayden (Virtual)
  - Jim Bowman (Virtual)
  - Shelley Tims Grant (Virtual)
- **UNOS Staff**
  - Robert Hunter
  - Stryker-Ann Vosteen
  - Lauren Mauk
  - Delaney Niles
  - Alex Carmack (Virtual)
  - Angel Carroll (Virtual)
  - Kevin Daub (Virtual)
  - Courtney Jett (Virtual)
  - Isaac Hager (Virtual)
  - Joann White (Virtual)
  - Kelley Poff (Virtual)
  - Krissy Laurie (Virtual)
  - Kristina Hogan (Virtual)
  - Kristine Althaus (Virtual)
  - Laura Schmitt (Virtual)
  - Lindsey Larkin (Virtual)
  - Meghan McDermott (Virtual)
  - Rebecca Murdock(Virtual)
  - Roger Vacovsky (Virtual)
  - Terri Helfrich (Virtual)
- **Other Attendees**
  - David Bearl (Virtual)
  - Ed Hollinger (Virtual)
  - Lisa Stocks (Virtual)

- Oyedolamu Olaitan (Virtual)
- James Trotter (Virtual)