OPTN Transplant Coordinators Committee
Meeting Summary
February 10, 2023
Chicago, Illinois

Stacy McKean, RN, Chair
Natalie Santiago-Blackwell, RN, MSN, Vice Chair

Introduction

The Transplant Coordinators Committee met in Chicago, Illinois on 02/10/2023 to discuss the following agenda items:

1. Policy Oversight Committee Update
2. Public Comment Presentation: Establish Member System Access, Security Framework, and Incident Management and Reporting Requirements
3. Public Comment Presentation: Expand Required Simultaneous Liver-Kidney Allocation
4. Public Comment Presentation: Identify Priority Shares in Kidney Multi-Organ Allocation
5. Public Comment Presentation: Ethical Evaluation of Multiple Listing
6. Public Comment Presentation: Continuous Distribution of Kidneys and Pancreata
7. Public Comment Presentation: Optimizing Usage of Kidney Offer Filters
8. Public Comment Presentation: Continuous Distribution of Livers and Intestines
9. Public Comment Presentation: National Liver Review Board (NLRB) Guidance for Multivisceral Transplant Candidates
10. Public Comment Presentation: Align OPTN KPD Blood Type Matching Policy and Establish Donor Re-Evaluation Requirements
11. Open Discussion

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

1. Policy Oversight Committee Update

The Committee received an update from the Policy Oversight Committee (POC) from the Committee's Vice Chair, who is a member of the POC.

Presentation summary:

The presentation involved 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 visiting Board of Directors member noted her experience while previously serving on the POC and currently serving on the Board. She stated that due to the resource constraints and budget situation,

there have been recent discussions about the number of projects approved by the POC that require programming.

The Vice-Chair added that these are ongoing discussions with the POC. She added that it is challenging due to the urgency of large projects such as continuous distribution and other projects that need to be prioritized to improve the system. She added that part of the "benefit score" discussion includes quantifying the programming hours. There are so many project ideas and setting the priorities for the organization within a certain budget is challenging. The visiting Board member commented that implementing the benefit score will be a big help with this process.

A member noted that some of the project prioritization also needs to occur at the committee level. Another member added that implementing too many large projects creates a burden for members.

2. Public Comment Presentation: Establish Member System Access, Security Framework, and Incident Management and Reporting Requirements

The Committee received a public comment presentation on the proposal to *Establish Member System Access, Security Framework, and Incident Management and Reporting Requirements* from the Network Operations Oversight Committee (NOOC).

Summary of discussion:

A member commented that this is a worthwhile policy proposal, but the initial contact between member institutions and information technology (IT) departments may be confusing. He added that transplant center members are more clinical with no direct contact with the IT leadership within their healthcare system, which is where the expertise exists to help implement future requirements. He further added that larger institutions are probably better prepared for these proposed requirements, while the smaller organizations such as OPOs and histocompatibility labs are not. Lastly, he didn't think that the second site administrator requirement would be an issue to implement.

A member asked if organizations already utilize third party auditors, it seems redundant to require another auditor and creates extra burden on institutions. The NOOC Chair responded that the committee would know more about how this will work following an initial readiness assessment, but the goal is not to make it redundant. He added that there are discussions about how the audits will be performed and whether they might be different depending on the member type and their current IT security processes. Lastly, he noted that larger institutions might be larger "targets" for system attacks than a small HLA lab.

A member suggested developing a toolkit or frequently asked questions (FAQ) to assist members during discussions with their IT departments about these proposed requirements. The NOOC Chair acknowledged that communicating with IT security can be challenging due to the complex nature of their work. He added that the plan is not to reinvent the IT security framework, but to ensure all the safeguards are in place and incident responses are timely.

A member asked if the training discussions would focus on more in-depth training for member IT contacts so they are more engaged if something were to occur. The NOOC member noted that the training will need to be tailored to meet the needs of the various levels of expertise of the staff.

A member noted that her organization conducts "tabletop exercises" for emergency planning and asked if the OPTN would provide such a guide for how to handle an emergency. The NOOC Chair thought that was a great idea and noted that the OPTN is discussing what resources could be made available to members to prepare for and implement potential security changes.

A member commented about the security requirements for the different devices used by members. For example, accessing the system on a hospital owned computer is much different than a personal device such as a cell phone or tablet. The NOOC Chair responded that it will be part of the implementation discussions. For example, accessing "read only" information might require different levels security than electronic medical records (EMRs) and application programming interfaces (APIs) where information is being uploaded or transferred.

A member commented that she works at a large institution and healthcare system with a robust security framework, so a lot of what is being proposed is standard for them. Her concern was the proposed timeline with implementation starting in early Spring 2023. Without clarifications regarding the auditing or guidance documents to provide to IT departments, she stated that it will be difficult for member institutions to implement. She added that at larger institutions, the transplant programs have little control over the security framework. She further commented on the scope of authority and suggested that since IT security is a national problem, maybe the Centers for Medicare and Medicaid Services (CMS) should provide oversight.

A member suggested conducting a readiness exercise before trying to identify mandates. This could help inform questions and provide implementation information for a more robust public comment proposal. She further added concerns about significant post-public comment changes being added without public input. The NOOC Chair noted that this needs to be a collaborative effort as the requirements are implemented using a phased approach.

A member provided an example of a ransomware attack at a large healthcare system that prevented transplants from being performed and shut down hospital operations. She suggested that the NOOC could provide some resources or guidelines for transplant programs to provide access to care in the absence of access to EMRs. The NOOC Chair responded that there have been discussions about best practices but there is concern about trying to dictate organizations handle EMR breaches. The NOOC is trying to identify potential gaps and risks and how to best mitigate them. IT staff noted that efforts are being made to allow members to work "offline" if the systems are down to continue providing transplant care. A member suggested doing a pilot before imposing policy requirements that could be operationally challenging.

Another member agreed that the timeline is short and suggested delaying the implementation. He also questioned if the NOOC anticipated the site security administrators and information security personnel would be the same individuals. The NOOC Chair responded that it might be determined at the member level.

The member noted that his institution has an HLA department as well as the transplant center and asked if they would have separate requirements. The NOOC Chair responded that there might be some overlap, but since they are considered separate member groups then they would each have to meet the requirements. He added that the goal is to work together to address these concerns, but there is also pressure to move this proposal forward in a timely manner.

A member asked if the network is down at a hospital, what policies need to be adjusted to allow transplant programs to perform transplants. The NOOC Chair noted that there is a difference between performing transplants and OPTN reporting requirements. He added that the NOOC is aware that transplant programs are different than the rest of the institution. There needs to be a balance between remaining operational without imposing prescriptive OPTN oversight. This issue is not unique to transplant, and it is a fast-moving environment to identify threats. He stated that it is challenging to standardize security across multiple domains.

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.

3. Public Comment Presentation: 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 noted that late turndowns in the OR can complicate allocation. For example, if a liver is turned down and the next patient on the match run is a simultaneous liver-kidney candidates, the kidney may no longer be available. She added that this creates challenges for OPOs who should not be required to hold the kidney for a potential SLK candidate further down on the match run. The MOT Committee representative noted that this scenario will be addressed as part of the MOT Committee's concept paper.

A member added that pediatric programs like to bring their pediatric candidates into the transplant center as early as possible when there is a potential offer. It can be frustrating with late declines in the OR for MOT. She suggested that once OR time is set, then the OPO can't allocate to another MOT candidate if there is a late decline. She further expressed concern about how MOT might negatively impact highly sensitized and 0-ABDR candidates. The MOT Committee member noted that it is a challenge to address kidney alone and MOT to find the right balance. She noted that the increase in MOT is anticipated to be relatively small with 60-70 additional transplants per year, so the general impact on 25,000 kidneys per year is relatively small. She also noted that the MOT Committee is also addressing the kidney alone issue with a concept paper currently out for public comment. This includes discussion about when allocation needs to be closed. She asked TCC members if they had any suggestions on an appropriate threshold to allocate only to kidney alone candidates.

A member thought that the MOT proposals should have been combined since one could potentially impact the other. She acknowledged that it is complicated to establish rules while also allowing flexibility as individual cases change. However, she expressed frustration because there have been times when her center has called in a patient three times without getting the kidney. Some of these patients live 4-6 hours away. Additionally, case times have been increasing to the point where it could be 2-4 days after the initial offer before the donor goes to the recovery OR.

A member asked if there would be an impact on pediatric liver and kidneys. The MOT Committee member noted there might be a small decrease in access in some regions such as 3, 6, 7, 8, and 10, but it should be minimal due to the low numbers of SLK transplants. She added that it is sometimes challenging to model the impact when there are allocation numerous changes occurring.

A member suggested having the ability to "opt in" similar to expedited liver offers. This would allow transplant centers to identify when a surgeon is unwilling to accept a liver without a kidney. This could include a donor selection preference of "must receive MOT" or "willing to accept liver alone."

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. Public Comment Presentation: Identify Priority Shares in Kidney Multi-Organ Allocation

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 commented that it was good to see the overall number of SLK transplants decreasing, which might be related to the previous SLK policy changes which included the safety net. She further added that the best utilization of organs is important and post-transplant outcomes need to be monitored. For example, if a heart alone patient passes away when a heart-kidney transplant would have provided the best chance of survival. Lastly, she added that late turndowns are an issue and commented that if someone receives a kidney offer then it should not be reallocated to another candidate.

A member noted that pediatric patients make up 1% of transplants so they should be prioritized along with high CPRA and medically urgent candidates. She added that when a kidney-pancreas is involved it becomes more complicated if the second kidney is being allocated as part of an SLK. She noted that there have been circumstances where her center is not offered the kidney but is identified as a backup. The member noted that her center still must be prepared if they are the backup offer to mitigate cold ischemic time if they eventually become primary.

A member noted that from a pediatric standpoint, seeing 1-20% KDPI kidneys going to MOT candidates is difficult because pediatric candidates face the potential for additional kidney transplants if they don't receive the best possible kidney. She added that laterality is also an issue for pediatrics because anatomy, whether it is a vessel or size issue, can impact organ offer acceptance.

A member asked if the MOT Committee had discussed prior living donors. Another member commented that prior living donors already receive additional priority for deceased donor kidney alone, but they are currently not one of the groups identified for priority in the proposal. The MOT Committee member responded that she would bring this comment back to the MOT Committee.

A member commented that with the safety net going into place for heart and lung, should the MOT Committee review the impact of those changes before moving forward with these policies. The MOT Committee member responded that the number of heart-kidney and lung-kidney transplants are relatively small. The number of SLK transplants decreased slightly following the implementation of the SLK safety net, and the hope is that a similar trend will happen with thoracic organs to make more kidneys available for kidney alone candidates.

A member noted that it is always a struggle to balance waitlist times with long-term outcomes. Each organ system prioritizes candidates differently, with only lung considering long-term outcomes. Another member added that a separate scoring system might be beneficial or include an attribute for MOT in the development of the continuous distribution models. A member added that it would be nice if transplant centers could indicate willingness to accept a single organ or dual organ or if the medical complexity of a candidate requires them to receive both organs from the same donor.

The MOT Committee member asked the TCC members if the safety net offers enough priority for individuals on dialysis or with severe kidney disease. Several members stated that they thought it does provide appropriate priority.

A member commented that if a candidate receives a kidney through the safety net within the first year, they should be excluded from the outcomes like simultaneous transplants. Currently there are reservations about moving forward with a kidney transplant early because programs are worried about the outcomes in that first year.

The MOT Committee member asked if there were any administrative burdens when using the safety net. A member noted that it is a positive thing at her center based on the experience with liver. She added that it is a seamless process from the coordinator's perspective.

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.

5. Public Comment Presentation: Ethical Evaluation of Multiple Listing

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 agreed with the Ethics Committee's findings because her transplant program recently had a patient who was listed at four different centers and had the resources to travel anywhere to get a kidney transplant. At the same time, she had a patient who lives two hours away and doesn't have transportation to get to the transplant center to receive care. She also opined that patients who multiple list are typically wealthier, more educated, and have the resources to travel. She also noted there is a difference of opinion amongst the coordinators at her program. Coordinators who have been at the transplant program for less than two years tend to favor multiple listing while the coordinators who have been around for ten plus years are opposed to it.

Staff noted that about 7% of patients on the waiting list are multi-listed. Staff added that some early comments have focused on what is preventing the other 93% from multi-listing.

A member commented about the differences in organ offer acceptance practices across programs. Some centers have access to normothermic regional perfusion (NRP) technology or provide donation after circulatory death (DCD) options that could allow quicker access to a transplant. She added that it is challenging to educate patients and be transparent about the options available to them. For example, if a patient is listed at a transplant center that does not routinely use DCD organs, the patients might not be aware of it. Therefore, the advantage of multi-listing is access to more organs than what is available at their "primary" center.

Staff noted that data analyses show that more than one half of patients were transplanted at the secondary center. The Ethics Committee discussed strategies for allowing multiple evaluations but ultimately getting the patient listed at the transplant program that gives them the best opportunity for transplant. The Ethics Committee acknowledges that socioeconomic disparities might create barriers to this approach.

A member agreed that socioeconomic challenges for multi-listing will likely prevent patients from getting multiple evaluations. Patients can spend a lot of resources at one center which will restrict them from accessing evaluations at other centers. Another member agreed that patients who have the resources for multiple evaluations are the same individuals who will seek multiple listing.

A member commented that multiple listing is creating a system where the patient is going to the organ while allocation policies should be getting the organs to the patient, otherwise there will always be disparities in access. Improved allocation could eliminate the need for patients to multi-list.

A member noted that health insurance also has an impact on multiple listing. For example, pediatric Medicaid patients in Kansas only have one transplant program in Kansas City, while Missouri patients have both Kansas City and St. Louis. Patients in certain areas of Oklahoma must get a medical exception

in order to seek transplant services in Kansas City. Another member noted that pediatric Medicaid patients in New Hampshire, Vermont, and Maine must travel to Boston, further illustrating that some patients that have no control over where they seek transplant services.

A member also noted that pediatric patients might have less flexibility in their schedules for appointment. For example, they might be limited to summertime due to school schedules. She added the same might be true for adults with higher education, as they might have greater flexibility with their job schedules or more access to time off. A member noted that while we can't control these types of disparities, but we can control the utilization of organs.

A member asked if the multi-listing data could show the geographical locations for the multiple listings. For example, are these candidates getting multiple listed near their homes or across the country. If it is occurring locally, then it could be more of an educational issue than an economic one.

The member also added that establishing exceptions for such things as medical urgency could open up legal challenges for patients that also want this option. Staff noted that the Ethics Committee looked at the difference between the percentage and rates of patients that were transplanted within their 250 nautical mile acuity circle versus outside the circle. There was a varied result between kidney and liver and the committee is trying to determine if the multi-listings carried over from the previous allocation policies. She added that the Ethics Committee found that the average driving distance between the primary and secondary centers was 100 nautical miles.

A member noted her experience working at a kidney transplant program in Detroit which only had one OPO. A patient could drive to Toledo and get a transplant quicker. However, those with limited insurance options do not have that opportunity. She added that patients have the right to be multi-listed, but insurance might restrict the practice and some transplant centers will not allow multi-listed patients.

Staff noted that the Ethics Committee looked at the percentage of transplant centers that had patients multi-listed and there were several centers without any multi-listed patients. Committee members shared differing experiences about whether their centers allow multiple listing. A member noted that multi-listing makes sense in certain situations such as candidates living in multiple locations or a pediatric candidate with parents living in different parts of the country.

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.

6. Public Comment Presentation: Continuous Distribution of Kidneys and Pancreata

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 about the modeling results that show the median distance increase for pediatrics. She commented that her program's practices will not change because they don't accept kidneys from far way unless it is for a difficult to match candidate. The Kidney Committee member agreed that the modeling does not represent changes in behavior.

A member commented about trying to balance risk of mortality on the wait list versus long term outcomes. For example, black candidates on the waitlist are often referred late and having a higher risk

of death on the waitlist. Additionally, when you consider other comorbidities, they have less likelihood of long-term survival which makes it challenging to balance mortality and outcomes.

The Kidney Committee member agreed that it is challenging to prioritize one attribute over another based on what is important to certain groups. He emphasized the importance of participating in the prioritization exercises to help inform future decisions by the other committees working on continuous distribution.

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.

7. Public Comment Presentation: Optimizing Usage of Kidney 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 asked if transplant centers get to choose the filters they want or is it based on acceptance practices. The Operations and Safety Committee representative responded that transplant centers control their own filters, and this proposal is proposing "default filters" based on the center's acceptance history.

Several members expressed concern about the filters being applied every three months. This will create more work for transplant centers, especially aggressive centers that do not want any offer filters. The Operations and Safety Committee representative responded that the three-month period was an effort to increase usage without creating a long time period that would reduce the benefit of offer filters. She did note that acceptance practices could change during that time period and a certain filter could be excluded from future default filters.

A member asked if the offer filters were center or candidate specific. The Operations and Safety Committee representative responded that the filters are program specific, but programs can adjust them at the candidate level.

A member complimented the Committee on taking the feedback from the previous public comment period and applying it to this proposal. She recommended retaining the ability for transplant programs to modify the filters but expressed concern about the three-month period and recommended six months. Applying the filters every three months would be burdensome for transplant programs. She also recommended that the OPTN create a report on the types of offers accepted or missed by transplant programs. Lastly, she suggested adding the ability to apply filters based on which surgeon is on call.

The Operations and Safety Committee representative noted that the Committee has heard additional feedback about changing from three months to six months. There have also been discussions about allowing programs that actively use offer filters to go six months while requiring centers that simply turn them off every three months to remain on a three-month schedule.

A member supported the exclusion of certain patient types from the default filters. She also suggested looking at a certain threshold of offers instead of a strict timeframe to reduce the burden on smaller programs.

A member commented about the potential impact of the new Membership and Professional Standards Committee (MPSC) metrics on offer acceptances. For example, offers that are filtered off are excluded

from the acceptance model. And if a transplant center removes all the filters and then does not accept offers, they are at risk of being identified for MPSC review.

A member asked if there were plans to apply filters to other organ types. The Operations and Safety Committee representative responded that this has come up in prior discussions but right now the focus is on kidney offers.

A member thought it was great having the ability to select yes or no to DCD donors. She added that it would be nice to apply a combination of filters at the candidate level, such as an age or distance for DCD. Staff noted that the first step would be determining factors that would be applicable to each organ and utilizing the same pattern that already exists for this tool and the offer filters explorer.

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.

8. Public Comment Presentation: Continuous Distribution of Livers and Intestines

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 commented that after taking the liver prioritization exercise, she didn't think the "candidate waiting greater than 10 years" was applicable for liver. The Liver Committee Vice-Chair noted that the prioritization exercise was modeled after the kidney exercise, and that 4-5 years would probably be more realistic. He added that waiting time is currently only used as a tiebreaker for liver allocation.

A member appreciated the attention to population density since her transplant center is located in Florida and surrounded by water.

A member asked about the optimized predication of mortality (OPOM) model being discussed by the Liver Committee and how that would be a big shift from MELD/PELD. The Liver Committee Vice-Chair responded that MELD is widely known by the community that even minor changes might get pushback. For example, adding serum sodium several years ago and recently adding female sex and albumin. He added that one of the biggest criticisms of OPOM is the number of variables and how they are not all different variables. There is also concern about changing to OPOM at the same time as continuous distribution, and how there is no corresponding OPOM score for pediatric candidates. However, he noted that OPOM does have several advantages. One is that OPOM can be more easily updated and will also incorporate tumor priority without the need for exceptions. A member noted that a lot of resources could be freed up nationally by reducing the number of exceptions.

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. Members are also asked to participate in the Values Prioritization Exercise (VPE).

9. Public Comment Presentation: National Liver Review Board (NLRB) Guidance for Multivisceral Transplant Candidates

The Committee received a public comment presentation on the proposal on the *National Liver Review Board (NLRB) Guidance for Multivisceral Transplant Candidates* from the Liver and Intestinal Transplantation Committee.

Summary of discussion:

A member expressed support for the proposed MMaT+6 exception score with an increase of 3 points every 90 days. She noted that in southern California that would put candidates near a MELD of 40 where MMaTs are already high.

Another member expressed support for the changes and commended the Liver Committee for refining the guidelines for NLRBs. She appreciates the rule clarifications and applicability with the way MOT candidates are handled.

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.

10. Public Comment Presentation: Align OPTN KPD Blood Type Matching Policy and Establish Donor Re-Evaluation Requirements

The Committee received a public comment presentation on the proposal to *Align OPTN KPD Blood Type Matching Policy and Establish Donor Re-Evaluation Requirements* from the Kidney Transplantation Committee.

Summary of discussion:

A member expressed support for the timeframes being proposed in the policy. She did express concern about the donor testing portion being confusing. There are other infectious disease testing being tested for and her center just repeats all the testing at the same time.

A member noted that they re-evaluate their donors past one year for other KPD programs, so it is acceptable to retest for infectious diseases. She also supported not retesting for CMV and EBV if the donor previously tested positive.

A member noted that her only concern with this proposal is regarding the written consent requirement. She acknowledged that informed consent is a necessary part of patient centered healthcare, and healthcare providers should be having ongoing discussions with all patients based on their needs and when education is required. However, she believes that what is being proposed is not consistent with Policy 14.3, which requires signatures prior to organ recovery, not initiation of evaluation. Additionally, requiring a signature at the time of evaluation is not feasible when evaluating donors outside of the local area of the transplant center and creates an administrative burden that provides no clear benefit.

Staff clarified that OPTN policy regarding written consent doesn't prohibit the signature from being done electronically. The member appreciated the clarification but added that some systems don't allow that option due to concerns about HIPAA rules, so trying to operationalize this without a proven benefit is challenging. She added her concern about the value of getting signatures at various points throughout the process.

A member added that patients should not be required to drive from far away just to provide a signature. Another member agreed and added there is a potential for losing donors if they don't want to travel.

A member noted there are no informed consent signature requirements for listing, other than for blood type or for high KDPI kidneys. She added that some states might require an actual signature for informed consent, but overall informed consent is more than simply getting a signature, especially in the age of a pandemic and telehealth options. Another member added that a signature does not mean a patient understands or reads a document. Another member asked if the National Kidney Registry (NKR)

requires an annual informed consent and the response was that only an annual re-evaluation is required.

A member noted that reassessment requirements should be what is clinically appropriate. Members agreed that every year is appropriate because so much can change. Weight, blood pressure, and other medical history can change over the course of the year. A member noted that reassessment should be based from time of registration.

A member noted that as a living donor representative, re-evaluation at time of listing or anniversary of last testing should be considered. This is because a donor could be registered before completing the evaluation. Staff noted that the donor ineligibility component will be automated, so the system requires a date to calculate the 30-day grace period and asked what the appropriate date should be for this calculation. Members agreed that the registration and active date should be the same following the completion of the donor evaluation. A member noted there could be recipient factors that could impact the timing of this. Lastly, a member noted that the OPTN requirements should strive to align with the NKR requirements.

Members discussed what the appropriate date should be and recommended the registration date. This will allow the evaluation to be completed, as currently required in policy. A member asked if the program is responsible for entering the re-evaluation date. Staff noted that there will be one data field where the transplant program can enter the date.

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.

11. Open Discussion

The Committee had a time for open discussion.

Summary of discussion:

eGFR Implementation

Staff noted that there are several tools being developed to assist members:

- Webinar for transplant professionals that will provide an overview of the policy, what is required, and some best practices.
- Website toolkit for patients and professionals – awaiting approval
- Updated sample patient letters based on letters created by transplant centers.
- Patient letters in different languages
- Direct links to the patient services line
- Frequently asked questions (FAQ) with the ability to create a PDF version. Staff noted that the patient FAQ is awaiting approval.
- Patient letters in different languages

Staff noted there have been approximately 95 wait time modifications requests with varying time requests. Staff is actively monitoring feedback and adjusting tools as needed by the community.

A member asked if there was going to be any changes to the requirements. Staff noted that the current policy was approved by the Board of Directors in December 2022 and implemented in January 2023. Another member commented that the post public comment changes were significant and created a huge administrative burden for transplant centers. She acknowledged the pressure to move quickly on this proposal and subsequent implementation due to the historical disparities. She opined that such

substantive changes should go back out for public comment to provide the community with an opportunity to weigh in. Now transplant centers have one year to meet the requirements and are not adequately prepared to accomplish all the tasks outlined in the policy, in particular those programs with a high percentage of African American candidates.

Staff agreed with the comment about the pressure to implement this policy change. Staff further noted that when presenting this project to the OPTN Patient Affairs Committee, the response was that the burden on transplant centers should not be considered because it is the right thing to do for patients. The effort to find the balance based on feedback from patients and transplant professionals has been extremely challenging for staff.

A member noted that the focus should be on getting the points to the patients, not sending a letter to every person on the list. She added that her center only has 16 patients on their list and can't imagine what larger centers are experiencing. She asked why pediatric patients were included since most patients have a eGFR greater than 20 before being listed. Additionally, sending a three-page letter to families trying to explain a complicated topic that is not relevant to them is unnecessary.

Staff noted that transplant centers are not required to use the sample letters provided. Additionally, staff noted that the committee discussed the notification letters and wanted to ensure that all patients that could have been affected were notified.

A member asked what happens if an individual self-identifies as black because they have a distance relative that was black. A member added that she has a mixed-race cousin who looks Caucasian, so how are members handling self-identified race.

A member commented that the requirement for the notification letter is too prescriptive. For example, why can't the pediatric centers that never use eGFR just send one letter explaining that nobody on the list was negatively impacted. Staff noted that the committee believed that to provide transparency and capture those adolescent patients approaching adulthood, the notification should be sent to everyone.

A member noted that he has had two Caucasian patients asking about the changes and how it impacts them. Another member responded that they weren't impacted by the previous race-based calculation, but it is an issue that might come up. She further added that it is a listing process issue and patients listed using a race-based lab value are disadvantaged. Staff commented that how patients are listed is another issue that will be addressed in the future.

A member commented that as a transplant professional this is a huge administrative burden. However, there are many patients who were unintentionally disadvantaged and should have been transplanted by now. She added that while 365 days might not seem like a long time to complete the requirements, it is a long time for those waiting for a transplant.

Staff acknowledged that implementation could have been better but will use this as a learning experience.

A member suggested that transplant candidates who have been listed the longest should have their waiting time modifications prioritized first.

A member asked if the requirements apply to new patients being added to the list. Additionally, are these eligibility criteria permanent for black candidates or only for a year. Staff responded that the current requirements are to review and assess the current list of patients. Additionally, the new policy passed in July 2022 will not include a race-based value. However, it does not prevent a new patient from coming forward with documentation that would qualify them for a waiting time modification.

The visiting Board member noted that it is challenging trying to explain why one center might take longer than another to complete these requirements, which might disadvantage some candidates.

Staff noted that some members have shared best practices where they provide the letter while having a conversation with the patient. A member asked why the OPTN didn't provide the education because some patients will get longer letters than others depending on how the transplant programs decide to notify patients.

A member suggested that future programming should be done so that transplant programs don't have to manually complete the forms.

PHS Guideline

A member mentioned the previous discussion regarding the data definition for Hepatitis B vaccination status. She asked about individuals that were vaccinated then are surface AB negative at transplant. Another member commented that new guidance/reporting process is not clinically significant.

A member noted that UNOS site surveyors have very literal interpretation on policies, but there are caveats that need to be accounted for in patient care. For example, a heart patient who was discharged but readmitted in 24 hours, we were cited because testing was not done for the second admission. There were probably no events that could have occurred with the recipient within 24 hours of the previous labs.

A member added that post-transplant infectious disease testing requirements create a lot of operational challenges since testing might be reliant on external locations. There was additional concern about the requirement that testing occur during the admission but prior to transplant. A member suggested aligning OPTN requirements with the PHS guideline.

Upcoming Meetings

- February 16, 2023

Attendance

- **Committee Members**
  - Angele Lacks
  - Ashley Cardenas
  - Ashley Hamby
  - Brenda Durand
  - Jaime Myers
  - Karl Neumann
  - Kelsey McCauley
  - Melissa Walker
  - Natalie Santiago-Blackwell
  - Rosa Guajardo
  - Valinda Jones
- **HRSA Representatives**
  - First Name Last Name
- **SRTR Staff**
  - First Name Last Name
- **UNOS Staff**
  - Courtney Jett
  - David Roberts
  - Lauren Mauk
  - Robert Hunter
- **Other Attendees (Presenters)**
  - First Name Last Name