OPTN Pediatric Transplantation Committee
Meeting Summary
August 18, 2023
In-Person in Detroit, MI and Conference Call
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Introduction

The OPTN Pediatric Transplantation Committee (the Committee) met in-person in Detroit, MI and via Citrix GoToMeeting teleconference, on 08/18/2023 to discuss the following agenda items:

1. Welcome, housekeeping, and icebreaker
2. Eliminate Use of DSA and Region from Kidney Allocation Two Year Post-Implementation Monitoring Report
3. Brief Introduction to Continuous Distribution
4. Continuous Distribution of Hearts Project Update
5. Update on Continuous Distribution of Livers and Intestines and Discuss Incorporation of Status 1B into Continuous Distribution
6. Update on the Continuous Distribution of Kidney Pancreas and Request for Feedback
7. Median PELD at Transplant (MPaT) Data Request
8. Ethical Analysis of Normothermic Regional Perfusion
9. Research's Role in the OPTN Policy-Making Process
10. Require Reporting of Patient Safety Events
11. Modify Offer Acceptance Limit
12. Wrap-Up and Discuss Taskforce on Efficiency

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

1. Welcome, housekeeping, and icebreaker

Committee leadership welcomed the Committee, gave a few announcements, and led an icebreaker activity.

2. Eliminate Use of DSA and Region from Kidney Allocation Two Year Post-Implementation Monitoring Report

The Committee heard a presentation on a monitoring report about the removal of Donor Service Area (DSA) and region from kidney allocation. More specifically, the Committee reviewed the metrics relevant to the pediatric population.

Presentation Summary:

The goals of the removal of DSA and region were to increase equity in access to transplant and minimize negative impact of broader sharing on organ utilization and system efficiency. The main policy changes that were implemented on March 15, 2021, to remove DSA and region from kidney allocation include:

- 250 NM circle to replace DSA and region
- Proximity points assigned based on distance between listing and donor hospital
- Increased prioritization for pediatric candidates and prior living donor within 250 NM of donor hospital

Conclusions from the *Eliminate Use of DSA and Region From Kidney Allocation Two Year Post-Implementation Monitoring Report*[1]:

- Notable increases in transplant rate for several subpopulations of pediatric candidates including:
    - All pediatric age groups
    - Black and Hispanic candidates
- All regions experienced a statistically significant increase in transplant rates except for regions 4, 5, 6, and 8
- Deceased donor kidneys are traveling farther, although about 95% are staying within 250 NM
- Kidneys are less likely to be transplanted within the same DSA of recovery as compared to pre-policy
    - Although 34.38% of transplants stayed within the same DSA
- Median cold ischemic time increased about 2.75 hours
- Rate of delayed graft function increased by about 1%
- Pediatric candidates were less likely to go on dialysis after listing pre-emptively

Summary of Discussion:

A Committee member had asked why there was regional variation regarding increases in transplant rates. OPTN contractor staff suggested that much of the variation may be due to the smaller numbers of transplants and registrations. In addition, geographical locations that may have been limited due to DSAs are now benefiting from its removal.

When looking at the Cold Ischemic Time for Deceased Donor Pediatric Kidney Transplants by Policy Era, a member questioned whether there was a separate visual or data set that measured the relationship between cold ischemia time and distance. While there was no data observing that relationship, the Committee determined that this would be an interesting factor to observe, especially with the onset of continuous distribution. Members also added that data analysis of elements such as delayed graft function by age, and factors such as cost could be interesting.

Considering there is a general trend of increasing transplant rates and steady discard rates, a member wondered how they could conclude that this policy has had a positive impact. More specifically, they questioned whether the trend of increasing transplants would be a better comparison than the two-year pre-policy implementation data. OPTN contractor staff agreed that the alternative comparison would have been helpful as well and noted that there were difficulties with the data that were brought on by Covid in the pre-policy era and CMS changes in the post-policy era. A member also added that if they were to do a monitoring report based on estimated versus actual impact, modeling assumptions would have to be used to make the estimates which also could be inaccurate.

In further discussion, a member suggested that it could be useful to use cohort data that predates the pre-policy cohort (March 16, 2019 – March 14, 2021) used in this analysis. They explain that this could provide a better understanding of the impact that the policy change had compared to external factors such as Covid-19.

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[1] Eliminate Use of DSA and Region from Kidney Allocation Two Year Post-Implementation Monitoring Report, June 22, 2023. https://optn.transplant.hrsa.gov/media/4mhfm3oq/eliminate_use_of_dsa_and_region_from_kidney_allocation_two_year_post_implementation_monitoring_report_2yr.pdf.

The Committee also discussed that this change to DSA and region was the result of mandates by the court. From this, the goal was to be able to share kidneys more broadly, outside of just the DSA. The data suggests that this is being achieved as seen through the increase in kidneys being shared regionally and nationally. This policy also had a positive impact on adults in race and ethnicity groups, as well as those in different geographical areas. Members shared concern that the policy change may have caused an immediate impact but may not be able to sustain change over time.

3. Brief Introduction to Continuous Distribution

The Committee heard a presentation that introduced the concept of continuous distribution which helps to further remove geographic boundaries and better match donors with recipients.

Presentation Summary:

The goal of continuous distribution is to be able to remove geographical boundaries and to allocate organs in a more equitable and agile way. Continuous distribution changes organ allocation from a classification-based system to a points-based system. Points are assigned to candidates in a more uniform manner and still consider elements such as medical urgency, sensitization, blood type, and more. Lung continuous distribution was implemented in March of 2023, however, the main charge from the OPTN Board is to get all organs on continuous distribution as well.

The main impact of continuous distribution on children is that it would focus on pediatric priority. More specifically, the framework prioritizes all candidates registered before their 18th birthday and allows them to maintain the priority after turning 18. Pediatric candidates will be allotted a considerable number of points for their pediatric status which will push their score higher. Continuous distribution will also consider the size and height of candidates, which may add points as well. In addition, as a candidate receives more priority, they will not only receive priority for organs near where they are registered, but they will also start to receive priority for organs that are further away

Summary of Discussion:

A member had asked what the goal of continuous distribution is, especially in the context of recreating the status quo versus trying to improve the overall system. The OPTN contractor staff stated that the way in which the continuous distribution framework has been constructed allows the system to better represent the goals of the overall community. In addition, this first iteration of the framework is meant to perform, at the very least, as well as the current allocation framework. Through the structuring of the organ-specific continuous distribution schemes, enhancement of the system becomes inevitable.

A member suggested that there is an opportunity to improve the system in the context of pediatric candidates, considering that there is a general sentiment that pediatrics should have more priority than they do currently. This priority can currently be seen in the case of lung distribution. With eighteen different pediatric candidates, none of them are lower than number 55 on a 1,100-person list. It is important to note that there is often prioritization for pediatric candidates due to the high mortality of potential lung candidates, this prioritization may not be the same across different organs.

A member questioned what would prevent changes to pediatric prioritization in the case that perception or opinions change within the community overtime. OPTN contractor staff agreed that perceptions may change and urged the importance of the pediatric community's and Committee's involvement through the development of continuous distribution and overall organ allocation.

4. Continuous Distribution of Hearts Project Update

The Committee heard an update on the OPTN Heart Transplantation Committee's progress on continuous distribution.

Presentation Summary:

The presenter introduced the purpose, goals, current state versus future state, and timeline for the development of heart continuous distribution. The heart continuous distribution system will include additional consideration for congenital heart disease, hypertrophic/restrictive cardiomyopathy, cardiac allograft vasculopathy, and waiting time on left ventricular assist device (LVAD), as well as attributes for sensitization and priority for prior living donors. An attribute for post-transplant survival is also under consideration, however, there is currently not an accurate measure for this. Pediatric candidates will receive priority in the pediatric attribute.

Summary of Discussion:

A member asked if all pediatric candidates will receive the same amount of priority, or if mortality differences associated with age and weight will be taken into account. The Chair added that the idea of patient access and priority for pediatric candidates is to provide access for the patients who have the smallest number of potential donors. The presenter answered that currently, the pediatric attribute is binary. The Chair asked the Heart Committee to explore options for rating scales for the pediatric attribute that are not just binary.

The Vice-Chair asked if a patient with a congenital heart disease who is listed after age 18 will receive any priority, and the presenter answered that the Heart Committee will be including additional priority for congenital conditions in the medical urgency attribute. A member responded that not all congenital heart diseases are equal in terms of urgency and mortality risk, and that the Heart Committee should consider prioritization within the medical urgency attribute regarding congenital conditions.

A member who was involved in a Heart Committee Workgroup added that the Heart Committee is taking an evidence-based approach to replicate and map the current prioritization of different conditions to a continuous distribution system. The presenter responded that the medical urgency attribute will not be binary, but instead a continuous scale in which each condition and the associated waitlist mortality falls somewhere on the curve. The presenter showed a slide of the Heart Committee's initial brainstorming of how the statuses will fall on the curve. The Vice-Chair stated that this represents a large change in how medical urgency will work for pediatric candidates, and noted that it is important for the Heart Committee to model how these pediatric urgency points will sort against other children and also against adults. The Chair responded that an increase in points may not translate directly to an increase in transplants for children, especially for those children who may receive less medical urgency points than they do currently via the status system, so this should also be modeled.

A member asked if there was any discussion about including total cardiac volume as a measure of patient access and matching donor and recipient size, and the presenter answered that the Heart Committee is not currently considering adding size considerations into the allocation scheme. Several members expressed a desire to be a part of the ongoing conversations about how to transition pediatric statuses and priority into heart continuous distribution.

5. Update on Continuous Distribution of Livers and Intestines and Discuss Incorporation of Status 1B into Continuous Distribution

The Committee heard a presentation on the OPTN Liver and Intestine Transplantation Committee's progress on continuous distribution and some specific concerns about ensuring adequate consideration for pediatric candidates.

Presentation Summary:

Continuous Distribution Update

This Committee update is the third public comment document from the Committee on the development of continuous distribution of livers and intestines. The purpose of this Committee update is to continue to inform the community about the development of continuous distribution, share the results of the values prioritization exercise (VPE) which was released as part of the previous public comment request for feedback, and solicit community input on specific topics including post-transplant survival, medical urgency scoring, and geographic equity. This Committee update also outlines the expected next steps in the development of continuous distribution.

Specifically to pediatrics, the Committee has expressed a desire to improve pediatric access to transplant and reduce pediatric waitlist mortality under continuous distribution. The VPE exercise results show similar emphasis from the community. The Committee is also using mathematical optimization analysis to better quantify, understand, and deliberate over tradeoffs between attributes, keeping in mind the specific outcomes each attribute intends to achieve. The Committee is having ongoing discussions about medical urgency, post-transplant survival, and geographic equity aspects for inclusion in continuous distribution. The Committee continues to agree that the allocation system already accounts for post-transplant survival appropriately and therefore does not intend to include a specific attribute for post-transplant survival in the first iteration of continuous distribution. As for medical urgency, the Committee has continued to engage with the developers of the Three-month Mortality Risk Prediction for End-Stage Liver Disease Patients (OPOM). There remains interest in OPOM's potential to better predict waitlist mortality, and MELD/PELD and OPOM are planned to both be included in the mathematical optimization analysis. Results will inform a final decision for a medical urgency score. The Committee has also broadened the scope for the geographic equity attribute to better account for donor supply and demand. The presenter noted that there are multiple identified attributes that relate to geography and impact each other. The Committee is working on the best way to incorporate this attribute into continuous distribution.

Incorporation of Status 1B into Continuous Distribution

The OPTN Liver and Intestine Transplantation Committee is working on how to convert the Status 1B priority status into the composite allocation score. All Status 1B candidates are pediatric, and this status is for candidates in urgent need of transplant but less sick than those in Status 1A. In the current system, all Status 1B candidates are right behind Status 1A candidates. The presenter provided background information on how the current system sorts candidates within Status 1B.

The Liver and Intestine Transplantation Committee intends to continue to give Status 1A candidates the highest priority in CD. The Status 1B population is more diverse and the Committee wants to make sure that feedback from the feedback from the pediatric community is considered. The presenter showed some examples CAS scores by candidate and status to show the different options of how candidates could be ordered. A question that the Committee is asking for feedback on is if there are any instances where a MELD or PELD candidate should be ranked above a Status 1B candidate (such as for blood type, proximity, etc). The Committee also asks for feedback on how much priority Status 1B candidates should receive relative to Status 1A, and how many points each Status 1B diagnosis should receive.

Summary of Discussion:

The Chair asked if there was an updated pediatric version of OPOM under consideration by the Liver and Intestine Committee, noting the importance of including improvements to pediatric scoring made to PELD-Cr. Staff noted that there is currently a pediatric version of OPOM, called POPOM. The Chair also

asked the Committee to consider how the new pediatric medical urgency scores will interdigitate with the adult scores. The Chair asked if OPOM would be a static calculation or if it would adapt over time, and the presenter answered that it will develop over time and be updated at regular intervals, but not at the time of each individual match run. The Chair noted that it would be important to consider the cohort size for pediatric candidates when making the updates to OPOM. A member explained that it is critical to consider how to explain the machine learning process to families.

The Chair asked if part of the discussion for the OPOM algorithm is to pull data from electronic medical records (EMRs) to be able to have the real-time data, and staff answered that while this has not been considered specifically for OPOM due to the specifics of the model, the OPTN has been having conversations about integrating with EMRs more broadly. A member asked if a pediatric specific EPTS score is being considered, and the presenter answered that the Committee is having ongoing conversations about whether to include EPTS into the first iteration of continuous distribution, but that if it is included, a pediatric specific model would need to be developed. The Chair noted that one option would be to give pediatric candidates the "best" EPTS score, similar to how kidney accounts for pediatric EPTS. A member commented that an additional factor in considering the inclusion of EPTS in liver continuous distribution is that it could be a proxy for a measure of difficulty for programs, and while it may not have a place in an allocation algorithm, it may be useful to include as a measure of program outcomes to account for tough cases.

The Vice-Chair inquired about any modeling for geographic equity, noting that the OPTN Kidney and Pancreas Committees had a fair amount of difficulty with developing a rating scale. The presenter answered that the Liver and Intestine Transplantation Committee has broken out the geographic equity into several pieces and is looking at each individually and how they all play together.

Status 1B

The Chair explained that there was a recent Workgroup that looked into Status 1B and affirmed the importance of keeping the three diagnostic groups within the status and transitioning the priority into continuous distribution. A member asked if any additional diagnostic groups should be considered for adding into Status 1B as it transitions to continuous distribution, and the Chair stated that the Workgroup did look into adding additional diagnostic groups and did not come up with any that necessitated adding to the Status. The member stated that the points assigned to each diagnostic group should be more carefully interrogated during the transition to continuous distribution. The Chair suggested doing modeling to determine how the candidates would sort, and noted that the chronic liver disease pediatric patients have the highest waitlist mortality.

Several members agreed that non-Status 1A or 1B candidates should always be below Status 1A and Status 1B candidates. The Chair stated that Status 1B candidates should be above the MELD/PELD candidates and below 1A candidates for the medical urgency score. However, members were in favor of looking into modeling where medical urgency status does not have absolute priority over CAS ranking. A member suggested keeping in mind the goal of continuous distribution, and asked the Liver and Intestine Committee to consider if they merely wish to replicate the current system in a continuous format, or if they would like to re-order the match run to take into account multiple variables across CAS scores.

6. Update on the Continuous Distribution of Kidney Pancreas and Request for Feedback

The Committee heard a presentation on Kidney Continuous Distribution and the results from the OPTN Kidney Transplantation Committee's second Organ Allocation Simulation (OASim) modeling results.

Presentation Summary:

The presenter introduced the status of kidney continuous distribution. The presentation will focus on pediatric priority and the second OASim modeling results specific to pediatric metrics. The presenter explained how pediatric candidates are currently prioritized and explained how this will change in continuous distribution. Priority for pediatric candidates will be achieved through the pediatric attribute, which will be binary. Pediatric candidates will be prioritized for all kidney donor profile index (KDPI) 0-34 percent kidneys and KDPI 35-85 percent kidneys from pediatric donors. Pediatric candidates will be assigned the lowest possible (best) estimated post-transplant score (EPTS).

The presenter explained the four scenarios that were submitted for OASim modeling, noting that the pediatric weight hovered around 15 percent for each scenario. The modeling results were summarized as follows:

- Pediatric candidates have higher access under all four scenarios including:
    - Within all CPRA groups
    - Within all Qualifying Time groups
- EPTS 0-20 percent candidates have higher access under all four scenarios
- Large increase in median travel distance for pediatric candidates
    - Note: Model assumes these offers will be accepted and does not consider system tools such as offer filters, acceptance criteria, etc.
- There appears to be a direct tradeoff between travel distance and access for pediatric candidates

The next steps for the Committee include further discussions on modeling results to refine attribute objectives, and additional optimization modeling. The Committee is currently exploring policy scenarios to determine if pediatric travel distance can be reduced while maintaining access. The median distance increases in the modeling because the modeling prioritizes pediatric candidates much higher than current allocation policy (even national pediatric offers are at the top of the match). Under current policy, there are some adult candidates who come before national kidney offers. One possible solution would be to more closely mirror current prioritization, which would bring the distance down.

The Pediatric Committee was asked to consider the following questions:

- How should the Kidney Committee consider the tradeoff between travel distance and high access?
    - Is increased distance for pediatric candidates tolerable if this allows them very high access?
    - Should the travel distance be reduced if it results in reduced access?
- Keeping in mind the following options below, what should the Kidney Committee keep top of mind?
    - Keep the currently proposed CD policies which very highly prioritize pediatric candidates, understanding that offers may increase, and look for solutions and tools to handle the increased offer volume
    - Explore modeling options that likely involve decreasing pediatric access so that only more local pediatric candidates are highly prioritized, to better mirror current allocation

Summary of Discussion:

A member asked if travel distance could be correlated with cold ischemic time, and staff responded that cold ischemic time unfortunately cannot be modeled, so distance is used as a surrogate. A member noted concern that pediatric access or transplant rate may not actually increase as projected if

transplant programs are declining many of the offers due to increased distance. The Chair agreed, and asked if a distance cutoff could be modeled to proxy acceptance behavior. Staff answered that the Committee did look into this, and found that the same transplant rate can be achieved when the model assumes no offers are accepted outside 250 nautical miles.

The Vice-Chair explained that the model results are concerning because the modeled transplant rates may not accurately reflect real-world scenarios because acceptance behavior cannot be accurately modeled, and in considering the two-year results from switching to acuity circles, increases in cold ischemic time and decreases in organ acceptance are predictable results from increased distances. Organ placement efficiency is a large concern, as well as overwhelming centers with offer volume. The Vice-Chair explained that the center-level acceptance filters do not provide adequate specificity to filter pediatric candidates, and that back-channel workarounds to increased distance for offers to pediatric candidates are concerning and should be avoided. The Kidney Committee should consider addition of candidate-specific offer filters to allow centers to handle offers that are too far away.

Staff asked the Vice-Chair about whether it would be more helpful to have updated acceptance criteria, or updated offer filters. The Vice-Chair responded that patient level filtering or sorting would be useful so that you can distinguish among highly sensitized candidates and among candidates who have been waiting for a long time, noting that the system must be created and validated for use specifically for pediatric candidates (not just an adult system with pediatric switches). A member noted that there are age-specific considerations within the 0-18 year olds, stating that a 17-year old candidate listed for a second transplant is very different from a baby. The Chair suggested having filtering based on age categories with associated maximum distances. A member added that increased access is very important for pediatric patients, however, there has to be a system in place to manage increased offers.

A member questioned if candidate-specific offer filters would actually inadvertently limit access for certain patients by introducing biases. The Vice-Chair noted that offer filters may re-establish hard boundaries, not provide access lower down the match run for offers that are less likely to be accepted.

The Vice-Chair asked if local transplants were modeled, noting that it is important to make sure that kidneys are offered to local candidates first before traveling long distances. The presenter and staff responded that the attributes all combine to create the composite allocation score (CAS) so it is possible that a pediatric candidate further away would show up higher on the match run, depending on other factors within that match run. A member asked that rural centers be considered carefully.

Members reached initial consensus that increased pediatric access is very important, and recommend the Kidney Committee move forward with solutions around managing increased offer volume. The Vice-Chair asserted that the solutions around offer volume need to be created at the same time as the proposal. A member commented that this discussion seems to be centered around risk tolerance, and that decisions around accepting organs from further distances should be a conversation with the candidate family. The Chair noted that this is one reason that patient-level filtering is important. A member explained that clearer data on cold ischemic time and distance, even if not included in the modeling, would be useful.

A member asked about modeling non-use rate, and the presenter answered that non-use rates cannot be modeled. A member explained that consistency in travel is another factor in this, and a member responded that Congress, HRSA, and the OPTN are working to improve travel logistics for organs.

7. Median PELD at Transplant (MPaT) Data Request

The Committee reviewed background on the problem regarding MPaT and discussed whether to submit a data request to be able to understand the problem better.

Presentation Summary:

The pediatric liver transplant community is concerned about a decreasing median Pediatric End-Stage Liver Disease (PELD) at transplant score, which is used to assign PELD exception scores. Committee leadership has discussed the concern with leadership from the OPTN Liver and Intestinal Organ Transplantation Committee and agreed to submit a data request to understand the situation before initiating a new project proposal.

If candidates meet specified standards, they can be approved for a MELD exception score that is assigned relative to median MELD at transplant (MMaT), or they can be approved for a PELD exception score which is assigned relative to MPaT. The goal of anchoring pediatric candidates' exception (MMaT) scores to MPaT is to make exception candidates' access to liver transplant more consistent with that of non-exception candidates. This allows children with exception scores to compete with adults for suitable donors. Since MMaT is calculated around each donor hospital, a decrease in MPaT could potentially cause a differential disadvantage—pediatric candidates with exceptions in areas where MPaT is less than the MMaT will fall behind adult candidates.

Potential data request metrics aim to answer the following questions:

- How many children does this impact?
- At what point does a decreasing MPaT start to impact pediatric access to deceased adult donors?
- How does the MPaT decrease impacts pediatric candidates assigned a PELD score?

Summary of Discussion:

A member of the Committee suggested that the data be analyzed based on geography or region since they expect to see some changes throughout the different locations. In addition, they offered that it would be helpful to look at the waitlist times to determine whether candidates were waiting longer because they could not get offers for organs that could be split. OPTN contractor staff agreed and added it to the data request. A different member also added that the PELD creatinine included an adjustment to have pediatric candidates compete as if they were eighteen years old. Therefore, it would be helpful to look at the changes to the creatinine score as well.

A member pointed out that for the metric that observes the point at which a decreasing MPaT would start to impact pediatric access to deceased adult donors, measuring the how many donors, candidates would lose access to if they drop below a certain MPaT point.

The Committee discussed how they hope that this is an issue that would auto correct over time. However, there is a potential for big geographic disparities in what kids can access. The Committee wants to ensure that they are being proactive going forward to avoid unintended consequences to the proposal and the community.

In an informal vote, the Committee decided to submit the proposed data request and metrics.

8. Ethical Analysis of Normothermic Regional Perfusion

The Committee heard a presentation on the Ethical Analysis of Normothermic Regional Perfusion that is out for public comment by the OPTN Ethics Committee.

Presentation Summary:

The mission and scope of the OPTN Ethics Committee (hereafter, the Committee) is to provide ethical analysis and guidance to the OPTN Board of Directors to support the sustainability of organ donation and transplantation in the United States and to maintain public trust. The Committee does this through

the development of white papers, the goal of which is to offer a comprehensive ethical analysis regarding a complex issue, often one regarding a new or evolving practice. This ethical analysis will lay the groundwork for any future development of a policy related to the practice; it itself is not policy. As such, the feedback sought on a white paper is to ensure the analysis is complete, not to develop consensus on the practice being analyzed.

This white paper conducts an ethical analysis of the organ procurement practice of normothermic regional perfusion (NRP) in the United States. NRP is a technique for circulating blood through organs after declaration of circulatory death and includes blocking vessels to the brain to prevent cerebral perfusion. As a surgical technique there is some evidence that it may increase utilization and longevity of organs. NRP has generated controversy, however, because it involves recirculation after circulatory declaration of death, and because of the need to demonstrate that no cerebral flow occurs during recirculation.

This white paper is not a referendum on clinicians, centers, or OPOs that engage in the practice of NRP, nor does it preclude a future of ethically practicing NRP in the United States. The white paper focuses on fully exploring and mapping the relevant ethical considerations relevant to NRP and the ensuing implications for the OPTN and broader transplant community. This exploration was supported by the proactive engagement of members from the community (see Appendices A-C), with representation from the OPTN Patient Affairs, Heart, Liver, Lung, OPO, and Transplant Coordinators Committees on a workgroup designed to review the topic, as well as discussing the analysis with the chairs of the American Society of Transplant Surgeons (ASTS) Ethics Advisory Committee.

The Committee examined NRP according to the ethical principles of do no harm, respect for persons, and utility, and concludes:

- NRP has great potential for utility, but this alone is not sufficient to demonstrate that a procedure is ethical.
- NRP raises concerns about compliance with the Dead Donor Rule, which requires that donors must meet criteria for death at the time of donation, to ensure that persons donating organs do not die by or for donation. The concern is that a person may legitimately meet criteria for determining death owing to permanent cessation of circulation at the time of death declaration, but that this criterion is subsequently violated when circulation is restored.
- NRP raises concerns about the potential for harm to the donor if cerebral flow occurs from the procedure. Additional evidence is needed to demonstrate that cerebral flow to brain is minimal.
  • In the interest of public trust, respect for persons, and transparency, authorization should include disclosure of recirculation through the heart (TA-NRP) and the potential restoration of any cerebral perfusion (TA-NRP and A-NRP), as well as considerations of meaningful differences from other donation approaches.
- Uncontrolled scenarios for NRP, in which circulatory death occurs unexpectedly and not after the planned withdrawal of life support, raise very serious concerns for respect for persons and proceeding too quickly from therapeutic treatment to organ recovery.

Summary of Discussion:

A member asked if the Committee discussed informing potential recipients of the possibility of receiving NRP organs, because of the potential of moral concern about the NRP process on the recipient end. The presenter answered that while this wasn't considered in the analysis specifically, recipient disclosures may be a general topic area that the Ethics Committee could take up in future projects and encouraged the member to submit a public comment with their thoughts.

A member described that they are at a center that currently does NRP and that in their experience, potential recipients are excited about the potential of NRP to reduce waitlist time, morbidity, and mortality. This member underscored the need for better information sharing about what OPOs are sharing with potential donor families. The Chair had some clarifying questions regarding the steps of NRP, and the presenter gave an overview of the process and the ethical considerations outlined in the analysis. The Chair explained that while donor families may not want explicit details, it is probably helpful to understand general timelines of the process.

The presenter asked if there were any considerations from a pediatric perspective that the Ethics Committee may have missed in the analysis. The Vice-Chair explained that one consideration may be that typically, resuscitation efforts are much more successful in pediatric patients, and wondered about the science of restoring perfusion in a child versus in an adult. The Chair agreed, and noted that it is important to consider the pediatric population specifically when doing additional studies on brain perfusion, and cautioned against simply extrapolating from adult data. A member explained that there are different procedures for determining neurologic death in children. A member suggested consulting the pediatric ICU and critical care community for helpful data on resuscitation in children.

A member explained that with pediatric donors, families typically undergo a longer decision and pre-recovery goodbye process. The Vice-Chair stated that it was reassuring to see that the Ethics Committee did not support uncontrolled NRP.

9. Research's Role in the OPTN Policy-Making Process

The Committee heard a presentation that outlined the main functions of the research department. They also reviewed the current and future changes to key metrics in monitoring reports.

Presentation Summary:

The research department's responsibilities include project management, maintaining data sets, completing data requests, engaging in scientific collaboration, data documentation and automation, providing committee support, conducting scientific research, and ensuring data quality. As a part of the OPTN contractor, the research department also plays a role in the policy process by providing analyses in support of policy change initiatives and for monitoring post policy implementation to evaluate whether key goals are being met.

OPTN Committee data requests will address research hypotheses that aligned with potential or current committee projects, it will determine the type of analysis needed to inform policy change or the creation of guidance documents, and it will aid in identifying relevant literature to address hypotheses as with analysis. The research department is shifting the framework for policy evaluation to provide more meaningful, faster access compared to a single static report. The department anticipates having dashboards available, which are currently in development. The goal of the dashboards is to replace the need to examine impacts of each type of data for various demographics in monitoring reports.

Summary of Discussion:

A Committee member stated that their key takeaway relates to the importance of the key metrics and how increasingly important they are. The key metrics are especially important because they can sometimes be sparse. The member adds that it is going to be crucial for the Pediatric Committee to make sure that they are advocating for relevant pediatric key metrics to be included in other presenting Committee proposals.

10. Require Reporting of Patient Safety Events

The Committee heard the OPTN Membership and Professional Standards Committee's (MPSC) proposal on Require Reporting of Patient Safety Events and discussed.

Presentation Summary:

The Organ Procurement and Transplantation Network (OPTN) contract requires the OPTN to notify leadership of the OPTN Membership and Professional Standards Committee (MPSC) and Health Resources and Services Administration (HRSA) of certain types of safety events within a specific time frame. However, OPTN policy does not explicitly require members to report some of these specific patient safety events. To ensure MPSC leadership and HRSA are aware of and can review potential patient safety situations, this proposal suggests updating OPTN policy to require members to report certain safety events. This proposal will also update the OPTN Improving Patient Safety Portal form instructions to list the events members will be required to report, making it easier for members to reference the events during the reporting process.

The following are the proposed patient safety events transplant hospitals will be required to report through the OPTN Improving Patient Safety Portal within 24 hours after becoming aware of the incident:

- A transplant of the incorrect organ into an organ recipient occurs.
- A transplant of an organ into the incorrect organ recipient occurs.
- A donor organ is identified as incorrect during pre-transplant processes conducted according to either *Policy 5.8.A: Pre-Transplant Verification Prior to Organ Receipt* or *Policy 5.8.B: Pretransplant Verification Upon Organ Receipt*.
- The potential transplant recipient is identified as incorrect during pre-transplant processes conducted according to either *Policy 5.8.A: Pre-Transplant Verification Prior to Organ Receipt* or *Policy 5.8.B: Pre-Transplant Verification Upon Organ Receipt*.
- An organ was delivered to the incorrect transplant hospital and resulted in non-use of the organ.
- The incorrect organ was delivered to the transplant hospital and resulted in non-use of the organ.
- An organ did not arrive when expected and resulted in the intended candidate not receiving a transplant from the intended donor because of the transportation issue.
- An ABO typing error or discrepancy is caught before or during pre-transplant processes conducted according to either *Policy 5.8.A: Pre-Transplant Verification Prior to Organ Receipt* or *Policy 5.8.B: Pre-Transplant Verification Upon Organ Receipt*

The following are the proposed patient safety events organ procurement organizations (OPOs) will be required to report through the OPTN Improving Patient Safety Portal within 24 hours after becoming aware of the incident:

- An ABO typing error or discrepancy is caught after the OPO's deceased donor blood type and subtype verification process, as outlined in *Policy 2.6.C: Reporting of Deceased Donor Blood Type and Subtype*.

The following are the proposed patient safety events all OPTN members will be required to report through the OPTN Improving Patient Safety Portal within 24 hours after becoming aware of the incident:

- Any sanction is taken by a state medical board or other professional body against a transplant professional working for an OPTN member.
- Evidence is discovered of an attempt to deceive the OPTN or the Department of Health and Human Services (HHS).

Summary of discussion:

The Chair asked when the checkpoint is for incorrect donor organ and incorrect potential recipient according to policy, and the presenter answered that it happens when the potential recipient and the organ are in the operating room as the final check, and that a near miss would be anything caught before that final checkpoint. The presenter explained that where the clock should begin on requiring reporting is something that the Committee requests feedback on.

A member asked if the recovery hospital is the correct unit to be reporting when a living donor is listed on the waitlist within two years after donation. The presenter replied that because the recovery hospital is required to track outcomes for their living donors for two years, they would know if this event occurred. However, if another source learns of a living donor being listed for a transplant, this proposal does not preclude them from reporting it.

A member commented that it may make more sense to also track if a living donor starts dialysis within two years in addition to living donors being added to the waitlist, because this could represent an urgent patient safety concern. Staff clarified that there is currently a requirement for reporting if a living kidney donor is listed on the waitlist or begins regularly administered dialysis within two years of the living kidney donation, and that the proposal does not change this requirement. The proposal adds a requirement for reporting if a living donor of *any* organ is added to *any* waitlist. The Chair asked the Committee to consider adding reporting requirements if a living donor of *any* organ begins dialysis within two years of the living donation for consistency and for ensuring patient safety. A member asked if ABO typing errors are common, and the presenter answered that while uncommon, it is important to report these events because they are such a patient safety concern.

The Vice-Chair commented that the reporting requirements for a transportation event may be too limited as this is such a high area of concern and certain events, such as organ lost in baggage or organ delayed due to flight delay, may be missed through these requirements. The presenter asked if members had a threshold of time in mind for delays that should be required for reporting. Members noted that this varies by organ and that this is important to keep in mind. A member suggested adding an expected arrival time, however, the Chair noted that this may be a difficult data point to add because the program and OPO would have to agree. The Chair asked the Committee to consider adding future requirements for transportation events that led to delay or to impairment of graft function, though this may be hard to define. The Chair also suggested making it clear that all entities (whether that be an individual, an OPO, or transplant hospital) are encouraged to report all patient safety events, even when not required by policy.

11. Modify Offer Acceptance Limit

The Committee heard a presentation on the OPTN Organ Procurement Organization (OPO) Committee's proposal out for public comment on Modify Organ Offer Acceptance Limit.

Presentation summary:

In 2018, changes to OPTN policy established limits on the number of organ offer acceptances for any one candidate per organ type. OPTN policy was previously silent on the number of acceptances for one candidate and the intent of the policy change was to reduce the number of concurrent acceptances. However, post implementation analysis concluded that "it is not uncommon for centers to enter two concurrent acceptances for a single liver candidate, and decision makers spend hours determining which organ, if any, to accept."

The practice of having multiple primary organ offer acceptances can lead to late declines, which can cause logistical issues for OPOs resulting in organ reallocations. This can lead to organ non-use, impact the quality of organs, and may negatively impact donor families with the increase in donor case time.

The OPTN Organ Procurement Organization (OPO) Committee proposes to reduce the number of primary organ offer acceptances from two to one for any one candidate per organ type. It is important to note that limiting the number of primary acceptances does not prevent transplant programs from receiving organ offers or affect their ability to decline and provisionally accept offers as necessary.

Summary of discussion:

A member asked about the mean time between first and second acceptances, and the presenter responded that this was not looked at in the analysis. The member suggested putting a cap on the timeframe for programs to have multiple acceptances out. The Chair asked how many of the multiple acceptance events were for pediatric candidates and for pediatric donors, and staff responded that this was not broken out in the analysis. The Chair responded that it would be helpful to take into account because reducing offer acceptance limit may impair access for highly sick and hard to match pediatric patients.

A member asked when the declines were occurring, and the presenter answered that the decline can happen anywhere in the process from before the operating room (OR) to post-cross clamp and that depending on where the decline occurs, it creates inefficiencies in the system. The Vice-Chair stated that it was shocking to see how many times this is happening in liver and that this represents a large inefficiency in the system. A member asked if data about whether the first or second organ is being turned down was taken into account, and suggested that this may provide important information about intent of the transplant program. For example, the first organ was turned down, this may be indicative of a center having a back-up plan for a difficult to match candidate. However, it could also be indicative of centers using out of sequence allocation in an inappropriate manner. A member suggested looking at this by region, and staff stated that this was taken into account in the analysis. Staff entered the data into the chat, and members remarked that it does not seem to be the case that this is happening more in areas that typically travel farther for organs.

Another member asked why this seems to be happening in liver so much more than the other organs, and the presenter answered that this may be due to recovery procedures, allocation practices, and centers receiving offers for liver in the time from original offer to procurement. This member suggested looking into this across organs and asked the Committee to consider developing a set of best practices.

A member asked if concurrent acceptances had an impact on non-use rates, and staff answered that non-use rates did not increase due to concurrent acceptances. A member asked if concurrent acceptances creates delays for procuring other organs, and the presenter answered that anecdotally, this does have an effect, and that it is more pronounced in cases where there is not a local procurement team. The Vice-Chair stated that what is often heard from liver programs is that concurrent acceptances are used for their most medically urgent patients, however, the data suggests that highly medically urgent patients only account for around 30 percent of concurrent acceptances. Members voiced concern for this policy, but did note that the out of sequence allocation is a large concern. Members also discussed the difficulty of evaluating this proposal for pediatric candidates because they were not separated out in the analysis. The Chair stated that if there is strong evidence that concurrent acceptances benefit very sick or hard to match patients, the Committee should consider allowing concurrent acceptances for these populations only. Overall, members were hesitant to provide support of this proposal without additional data.

12. Wrap-Up and Discuss Taskforce on Efficiency

The Committee was informed of the newly created Efficiency Task Force. This Task Force allows for a coordinated, collaborative, unified, and intentional effort to encourage OPTN system efficiency and improve utilization. The next steps in this process are to identify what work does or does not align with Task Force initiatives and to determine if specific projects may need to be put on pause.

A Committee member commented that this is an attempt to focus and evaluate whether the changes being made to the system that is intended to improve equity are counterproductive. There needs to be a balance between ideals and feasibility. OPTN contractor staff mention that while there is no set timeline, this is a Task Force that they are working to operationalize in a quick manner. Considering that this is moving forward to the Executive Committee within the early stages of its development, there are going to be uncertainties, however, this also provides an opportunity to offer input to the Board regarding what should be considered.

Members of the Committee agree that there would need to be pediatric representation from the provider and patient perspective because there could be unintended consequences of proposals or projects suggested. A member also added that it is critical to separate adult and pediatric data during analysis.

Attendees split off into different groups to discuss continuous distribution for kidney-pancreas and heart as it relates to the pediatric population. The heart group further discussed pediatric access and priority under the continuous distribution framework. A member stated that even though priority for pediatrics relating to medical urgency has historically been binary, under this structure kids who need a bigger boost according to their circumstances should be able to receive that if appropriate. For example, instead of awarding the same number of points for all pediatric patients, the system might implement points based on weight and other factors related to medical urgency. The main purpose is to spread out the status groups to ensure that the sickest patients truly get the priority for medical urgency.

A member asked the group if they thought the inclusion of post-transplant survival in continuous distribution was important. Members discussed how this would be a difficult factor to include because the population is heterogeneous.

The Committee further discussed how they will need to express explicit support for pediatric donors being allocated to pediatric recipients first, participate in the review board regarding exceptions, and contribute to the creation of this continuous distribution framework. When asked if review boards will be eliminated as a result of continuous distribution, OPTN contractor staff responded that each organ will be developing their review board to account for candidates that need an adjustment to their scores outside of what is accounted for in policy.

The kidney-pancreas group discussed the following:

- A need for the OPTN to collect additional data on the social determinants of heath (SDOH) to improve access to transplant
- the fact that cold ischemic time does not correlate well with distance
- A member noted that continuous distribution is a good idea, however, there needs to be adequate data to support it
- The need for additional pediatric representation in the decision-making process for continuous distribution
- The possibility of expanding or re-working the pediatric rating scale to better represent the population (consider a continuous scale)

The Committee was reminded of the next committee meeting taking place on August 23rd.

Upcoming Meeting

- August 23rd, 2023

Attendance

- **Committee Members**
  - Carol Wittleib-Weber
  - Neha Bansal
  - Geoff Kurland
  - Emily Perito
  - Gonzalo Wallis
  - Sonya Kirmani
  - Namrata Jain
  - Rachel Engen
  - Reem Raafat
  - Caitlin Peterson
  - Aaron Wightmann
  - Katrina Fields
  - Ryan Fischer
- **HRSA Representatives**
  - Jim Bowman
- **SRTR Staff**
  - Simon Horslen
- **UNOS Staff**
  - Alina Martinez
  - Betsy Gans
  - Cole Fox
  - Dave Roberts
  - Dzhuliyana Handarova
  - Erin Schnellinger
  - James Alcorn
  - Katrina Gauntt
  - Kayla Balfour
  - Kayla Temple
  - Keighly Bradbrook
  - Kelsi
  - Kieran McMahon
  - Krissy Laurie
  - Matt Cafarella
  - Meghan McDermott
  - Rebecca Brookman
  - Robert Hunter
  - Sally Aungier
  - Susan Tlusty
  - Thomas Dolan
- **Other Attendees**
  - Melissa McQueen
  - Andy Flescher
  - Mark Wakefield
  - PJ Gerhaghty
  - Rocky Daly

- Scott Biggins
- Shimul Shah