OPTN Patient Affairs Committee
Meeting Summary
September 12, 2023
Detroit, Michigan

Garrett Erdle, MBA, Chair
Molly McCarthy, Vice Chair

Introduction

The OPTN Patient Affairs Committee, the Committee, met in Detroit, Michigan, on 09/12/2023 to discuss the following agenda items:

1. Welcome and Introductions
2. OPTN President Update
3. Public Comment: Concepts for a Collaborative Approach to Living Donor Data Collection
4. Public Comment: Require Reporting of Patient Safety Events
5. Health Resources and Services Administration (HRSA) Modernization Update
6. Update on eGFR Modification
7. Public Comment: Ethical Analysis of Normothermic Regional Perfusion
8. Inactive Status Project Discussion

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

1. Welcome and Introductions

The Chair welcomed all committee members, visiting Organ Procurement and Transplantation Network (OPTN) Board Members, and contractor staff to the meeting. Each person in attendance was given a few moments to introduce themselves.

2. OPTN President Update

The OPTN President joined the meeting to update the Committee on concerns discussed at a previous OPTN Patient Affairs Committee meeting.

Presentation summary:

The OPTN President began by reviewing the HRSA Modernization Initiative, announced on March 22, 2023. The initiative seeks to improve technology, data transparency, governance, operations, and quality improvement in the transplant system. Currently, stakeholder engagement is underway seeking input on the initiative.

The OPTN President then addressed non-use of kidney. The five most common reasons for kidney non-use are:

- No recipient located/list exhausted (60.94%)
- Biopsy findings (15.7%)
- Other (10.36%)
- Anatomical abnormalities (3.19%)
- Poor organ function (2.73 %)

The OPTN is investigating the rising trend of organ non-use to identify root causes and develop solutions. As is the case with most elements of organ donation and transplant, the issue is complex and demands multi-faceted solutions from all stakeholders in donation and transplant. The goal is to get donated organs to recipients faster. Part of the solution to reduce organ non-use are offer filters, which allows transplant centers to filter out organ offers they do not accept based on the center's offer acceptance data. Currently 143 programs use offer filters for kidneys. The OPTN Board of Directors unanimously approved the application of default filters in June 2023, and the target implementation is for early 2024.

Predictive analytics is another tool to reduce organ non-use. This tool uses statistical modeling to show the potential impact on patient when accepting or declining an offer. The tool displays a predicted "Time to Next Offer" and shows patient mortality over that time. This is currently available to adult kidney programs. There is a Predictive Analytics Monitoring Report available, and updates are planned for the end of 2023. Community feedback is still being accepted for predictive analytics ahead of the update. The OPTN President also mentioned the Organ Offer Acceptance Collaborative and the DCD Lung Transplant Collaborative as other important resource generating opportunities to help reduce organ non-use.

Logistics and transportation issues were a concern raised by the Committee during previous meetings. The broader sharing of organs benefits the sickest patients, and the Federal Aviation Administration Reauthorization includes improvements for organ transportation.

The OPTN is also working to improve performance monitoring of organ procurement organizations (OPOs). The Membership and Professional Standards Committee (MPSC) has begun work on a project to enhance the monitoring of OPOs, both for standardizing processes and data collection. The Committee has a representative on the workgroup that is handling this project. The MPSC also implemented the offer acceptance metric for transplant programs in July 2023.

The OPTN President briefly reviewed the OPTN Task Force on Efficiency (the Task Force). Some of the priority areas of the Task Force are to decrease non-use of organs, scalability and replication of member processes, and consistency in allocation practice. While the Task Force is still being formed, patients will have representation on the Task Force.

The OPTN President then presented on a variety of patient communication topics. *OPTN Policy 5.3.C Informed Consent for Kidneys Based on KDPI Greater Than 85%* requires written consent by the patient for kidney offers with a KDPI greater than 85%. The OPTN President suggested the Committee could examine this policy and others to expand the acceptance rate of marginal organs. The OPTN President also suggested the Committee explore ways to better communicate the transplant journey to candidates, and to continue their work on inactive status communication.

The OPTN President then mentioned dashboards that are available, or that are being created, to help candidates select a transplant program, and for the public to monitor organ distribution. The presentation concluded with a review of the ongoing effort to separate the OPTN Board of Directors from the OPTN Contractor Board.

Summary of discussion:

A member thanked the OPTN President for sharing the information regarding the HRSA modernization effort and focus groups. They then asked if the results were going to be shared. The OPTN President responded that the OPTN Contractor might receive them, but they will go to HRSA. The OPTN President recommended the Committee ask HRSA if those results will be available during their presentation later in the meeting.

A member asked about out of sequence allocation, and observed there seems to be a lack of urgency to allocate kidneys because dialysis is a bridge to transplants so candidates are being skipped. The OPTN President responded that out of sequence allocation occurs when transplant programs are turning down offers and the OPOs are trying to place the organ somewhere that is likely to accept it. They may bypass certain programs after a certain period of time and reach out to more aggressive or local programs. This happens not just with kidneys but all organs. The OPOs are attempting to reduce non-use. This is an issue that needs to be explored more in depth. Another member asked if out of sequence allocation and its impact on multi-organ acceptance and declines. The OPTN President responded that the Task Force will be looking into this, and creating additional definitions regarding acceptance and decline. This should help in the understanding of accepting or declining an organ and whether it was patient or donor specific. Another member then asked if there was any analysis on the correlation between distance traveled, cold ischemic time, and allocation out of sequence. The OPTN President responded they do not have that data now, but they are trying to capture it.

A member asked what the OPTN position is on machine perfusion. The OPTN President responded that the machines are expensive and so it is up to individual programs to use the machines. But their use does increase organ availability in an innovative way.

The Chair pointed out the need for more granular information and asked why that is not being collected already. They then asked what the OPTN President sees as the benefit of involving patients in decision making. The OPTN President responded there has always been a challenge in asking programs to provide data. The process for collecting data can be rigorous and admin burden is a concern. The MPSC is looking at additional OPO data collection metrics. Data regarding allocation out of sequence may exist but the OPTN does not collect it, this is something the Task Force will examine. No two patients or organs are alike, the OPTN wants to engage the Committee more to determine what is important to patients so they can make better decisions for themselves. The OPTN President expressed a desire for the OPTN to provide more tools to help patients make those decisions.

The Vice Chair asked if transportation issues and equity are commingled topics. They then asked for an update regarding a letter sent to OPOs from the United State Senate Finance Committee regarding use of funds. The OPTN President responded that the OPTN changed allocation from circles to a more broader sharing concept. This solved some equity issues and better enabled the sickest candidates to be transplanted first. There were some unintended consequences, and those need to be examined prior to launching continuous distribution for other organs. The Vice Chair responded that this made sense but there are other equity issues, transportation is just one piece of it. The Vice Chair pointed out that getting people listed, particularly people of color, is another equity issue the Committee has been discussing. The OPTN President state neither they, nor the OPTN, were privy to the financial information that was in the letter sent to OPOs.

A member asked why it took so long to work with the FAA to move organs being transported by commercial flights back into the plane's cabin. The OPTN President responded that the policy change regarding organ transportation originally occurred when fewer organs were traveling by plane when allocation circles were in place. It became a bigger problem once those circles were removed.

A member asked why only 55% of transplant centers are using offer filters. The OPTN President responded that soon all transplant centers will be using them because they are now mandatory. The member then asked what measurable improvements have come out of the collaborative improvement efforts. The OPTN President pointed out that with certain collaborative improvement efforts there has been measurable improvements. The goal for the DCD Lung Transplant Collaborative was to increase transplant by 30%, and that goal has already been surpassed. The Vice Chair responded they appreciate

the collaboratives are starting to happen and exchanging best practices, and they would like to see more examples of the work they produce in the future.

A member asked what type of work is being done to improve the logistics of transporting organs. The OPTN President pointed out that while the OPTN contract does not specify logistics and therefore they have no jurisdiction over logistics, it is still a concern. The OPTN is working with the FAA to improve the transportation for organs.

The member then asked what work is being done to create a public dashboard, and how real time will the data be. The OPTN President responded that a dashboard has been created and is pending HRSA approval, but they are not sure how real time the data will be.

3. Public Comment: Concepts for a Collaborative Approach to Living Donor Data Collection

The Committee heard a presentation from the OPTN Living Donor Committee.

Presentation summary:

The OPTN Living Donor Committee has been discussing opportunities to collect data to analyze long term outcomes of living donation and barriers to living donation. Due to the barriers associated with collecting extended living donor follow-up data from transplant programs and the consensus that longer-term data are needed, the Living Donor Committee determined that some other entity, such as a registry, is better situated to connect directly with living donors. As such, the Living Donor Committee has been collaborating with the Scientific Registry of Transplant Recipients (SRTR) to develop a potential future state of living donor data collection. The concept paper explores and discusses the possibilities of this future state and seeks community feedback.

The Committee examined the concept paper and presented their findings:

- The Committee supports the ideas presented in the proposal but has some concerns about the practicality of the proposal.
- The Committee has concerns this could add more stress to the system, and increase the burden placed on transplant coordinators.
- There is also concern that adding additional follow-up could negatively impact potential living donors.
- The Committee was in agreement that collecting more data is needed to increase living donors and to assure potential donors of their long-term health.
- If there is not enough data to prove the proposal is likely to work, unburden the transplant centers and have SRTR take over at the point of donation, with a true consideration for abandoning the living donor candidate data collection if there is a dearth of evidence that will show it is likely to succeed-especially with respect to follow up on living donor candidates who decided not to donate.
- Find a way to reach out to donors that is more likely to be successful than surveys by email, telephone, and mail. Perhaps some of the human hours saved by limiting the proposal could free up humans to contact persons to obtain data. Perhaps by agreement to access their online health records, or some type of patient portal.
- Reach out to living donors on an annual basis for information. Get donors to agree to long-term follow up, with an opt out at any time.

Summary of discussion:

The Committee discussed the paper and provided the following commentary, which was entered into official public comment:

The OPTN Patient Affairs Committee would like to thank the OPTN Living Donor Committee for their work on this concept paper. PAC members include two living donors and multiple recipients of living donations. The committee has a unique perspective in that they personally understand both the need to increase living donation, and the barriers and concerns individuals have when deciding to become living donors. Potential living donors want to know if there is a risk of death during surgery, short-term risks and complications from surgeries, and long-term impacts, both physical and psychological, of donation. Potential living donors also want to know how this is going to impact their quality of life, their hobbies, and their families. They want to know what their health will look like in 5, 10, or even 20 years post donation. The data points discussed in this paper will go a long way in helping potential living donors better understand what they are signing up for. We do have some concern regarding the burden this could place on transplant centers. Inviting living donors to self-report frequently or for long periods of time could also be burdensome because they already give so much of their time to the process. Living donors are selfless individuals who willingly walk into a hospital healthy, and walk out compromised; simply asking them to provide more information that could help others make the decision to become living donors may be enough to get their buy in.

4. Public Comment: 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 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 Committee discussed the paper and provided the following commentary, which was entered into official public comment:

The Patient Affairs Committee would like to thank the MPSC for their work on this proposal. As a committee comprised entirely of patients, living donors, patient caregivers, and donor families, we wholeheartedly support this proposal. The Committee is supportive of the efforts to better track patient safety events, especially those which are not currently tracked but present serious patient safety concerns, such as near misses. Collecting this data through the reporting requirements may shed light on why near misses happen and opportunities to develop best practices to help standardize operations for transplant centers and OPOs. The Patient Affairs Committee recommends making the data collected as a part of this proposal as public facing as possible, and asks that the patient voice be included throughout the development of this project. The current proposal would require reporting a living donor who is added to the waiting list within two years of their donation; the PAC suggested perhaps that timeframe should be increased (5 or 10 years post-donation).

5. Health Resources and Services Administration (HRSA) Modernization Update

A representative from HRSA shared an update on the Administration's modernization efforts. The Committee then asked questions and held discussion.

Presentation summary:

The presenter explained the OPTN Modernization Initiative, which is centered on putting patients first, prioritizing information flow to clinicians, promoting innovation, and enhancing transparency and accountability by meeting the needs of all OPTN ecosystem members. A recap of the efforts to date on the modernization initiative was described, and the presenter noted that engaging diverse stakeholders and collaborating with industry experts is a top priority. A few details about the contract strategy were shared, and the presenter explained that program management, transition, and next generation contract options are being considered. The matching system will not be disrupted throughout this process.

Some ongoing patient outreach efforts were described, including outreach to listservs, HRSA's "contact us" form, focus groups, and other outreach possibilities. The presenter asked for feedback from the Committee on what should matter in the search for appropriate contractors.

Summary of discussion:

The Chair thanked the presenter. A member asked if any transition contracts would possibly extend into next generation contracts, and the presenter responded that it could be a bit of both and that HRSA is interested in fomenting creative ideas and innovation through the transition process. Another member asked how HRSA plans to use the results of their outreach and how the PAC could best get involved. The presenter responded that it is important to HRSA to solicit a broad range of feedback and consider those who are experts in their own experiences, and that all feedback is transmitted directly to the leadership of the modernization effort to inform progress and decision making. The member asked HRSA to engage the PAC throughout the process to leverage the expertise on the Committee.

A member shared that to them, it seemed like HRSA is rebuilding the car while driving it, and asked if there was concern about HRSA leadership having the capacity to manage these efforts. The presenter explained that HRSA is making sure that best practices in management strategies are being implemented so that HRSA has the capacity to support these efforts. The Vice-Chair expressed concern about ensuring fair and unbiased conversation and consideration of potential innovators and requested information on how the PAC should support that effort, formally or informally. The presenter responded, stating that public messaging and actions by HRSA strengthens HRSA's intent to do something different, and that the PAC can help by spreading the word and by participating in the ongoing outreach efforts.

A member described concern that HRSA is not adequately reaching out to important stakeholders who may not have access to the internet and concern that the organizations that are responding to the request for proposal (RFP) are already key players, which may shut out nonprofit and smaller organizations. The presenter shared that they plan to expand outreach and may have room for in-person stakeholder engagement and that HRSA's plan for an umbrella contract is a good way to create room for smaller organizations.

An OPTN Board member requested the development of a rubric for success to help evaluate bidders' experience in key areas and protection for the OPTN group, citing concern that members will not be adequately protected in the new legal framework. The presenter explained that HRSA evaluates bidders based on a set of evaluation criteria that is public, and that HRSA plans to distribute satisfaction surveys to the OPTN Board of Directors and to the OPTN at large to evaluate vendors. Also, HRSA plans to ensure that OPTN members are protected in the new legal framework.

A member questioned how policy development would work with multiple contracts and suggested HRSA engage the minority business development agencies. The presenter thanked the member for this suggestion and affirmed the importance of engaging these groups. On the policy development question, the presenter explained that policy is key, which is why HRSA is working to ensure independent, robust governance and ensuring strong IT infrastructure. The Chair asked the presenter to provide an overview of the relationship between HRSA and the OPTN, and the presenter shared a few details on this point. A member asked for more information about the RFP process, number of anticipated contractors, and plan for integration. The presenter explained that HRSA hopes to obtain many contractors responding to the RFP and will use best practices to integrate them and transition. The member added that the bigger a bureaucracy becomes, the harder it is to manage.

6. Update on eGFR Modification

The Ex Officio of the OPTN Kidney Transplantation Committee presented an update on the six-month implementation update: *Modify Waiting Time for Candidates Affected by Race-Inclusive eGFR Calculations*.

Presentation summary:

In July 2022 the OPTN implemented a rule that prohibits the use of eGFR calculations that include a race-based variable. As a result, waiting time for candidates affected by race-inclusive eGFR calculations must be modified. The implementation resources provided to the community include an educational offering in UNOS Connect, second iteration of candidate notification samples one and two which are available in Spanish, attestation sample documentation, FAQs for members and patients, an eGFR brochure for patients, monitoring of member questions and clarification requests, and individual implementation information sessions.

On March 15, 2023, there was an educational webinar regarding waiting time modification. This was attended by 195 out of 232 active kidney transplant programs. On July 12, 2023, there was an OPTN Collaborative webinar with 364 attendees including representatives from 147 active kidney transplant programs. Part of the July webinar registration process included a questionnaire that asked if their program had started the eGFR waiting time modification process, 87% of the 180 programs who responded said they had started the process.

The UNOS Connect course has been completed by 407 registered users, with 67 pending evaluation, and another 215 in progress as of September 5, 2023. Additionally, 9,875 modifications have been completed as of September 5, 2023. This is 31.5% of all black or African American candidates at 135 different programs, and 25 attestations. This is a substantial increase from February 2023 when only 109 modifications from seven programs with one attestation had occurred.

All black and African American kidney candidates registered on the OPTN waiting list are eligible for eGFR waiting time modification. This data is compiled by using the OPTN national data on the OPTN websites and includes registrations listed by ethnicity, Black, Non-Hispanic. It is not known how many black or African American candidates will qualify for a waiting time modification.

Summary of discussion:

A member expressed concern at the lack of hospital participation. The Presenter pointed out that programs still have a year and participation is mandatory. Contractor Staff responded that participation is being monitored, and some programs are small programs or pediatric programs, the contractor is doing outreach to these programs.

The Vice Chair asked why the lists are still being read in a dynamic way rather than static, since new candidates should not be subjected to the race-based eGFR test. The Presenter responded that there are candidates who are on dialysis for years before being referred to a transplant center or listed. Recently there was an individual who was on dialysis for eight years before being listed, and the transplant center located lab work from ten years ago that showed the race-based eGFR test had been used that impacted his candidacy. The center was able to provide a waiting time modification for that candidate. Even though race-based calculation is no longer in use, there are newly listed candidates who may have been impacted by it.

A member asked if this is helping to close the gap regarding African American donation. The Presenter did not have any data on this to share.

The Chair stated that the Committee discussed this issue three years ago and was glad to see a resolution on the matter. The Chair expressed concern that it took so long and suggested the process for matters like this should be expedited. The Presenter stated that the process in place ensures transparency and feedback from the public. They, too, would have liked to see the process move faster for a resolution, and that some people wanted the OPTN to release a statement asking programs to stop using the race-based calculation but a policy change with enforcement was needed.

A visiting Board Member asked if there was something for patients to see when they visit their programs, like a dashboard. Contractor Staff responded there is not but that the information is being shared at OPTN Regional Meetings that are attended by transplant programs.

A member asked if the average waiting time granted via modification increased, the member was recently told it averages around one to two years. The member also stated they recently learned that the most waiting time granted by modification was 17 years, has another candidate been granted more time than that following modification. The Presenter stated that those statistics are only a few weeks old and have not been updated. The member followed up and asked if there was any way to extrapolate an approximate number of modifications that have yet to be granted. The Presenter responded that this is unknown because of the complexity of uncovering the medical information that is needed to make an eligibility determination. Contractor Staff added that an additional monitoring report will be available in November and will include additional data.

A member asked if candidates who may not identify as completely Black or African American, but multi-racial are included as eligible for modification. The Presenter responded that it is self-identification of the candidate that is used as the determining factor. Contractor Staff added that notification from transplant centers to patients was required to go to all candidates regardless of race, that way those candidates who may not self-identify as Black or African American would still know they could be eligible.

A member asked for clarification, of the 9,875 modifications that were submitted there were approximately 300 to 400 who did not get their waiting times modified. The Presenter responded this is correct, sometimes the modifications are not granted for different reasons. For example, human error could have led to the incorrect test type being reported despite that test type not being used.

A member asked if the attestations submitted by programs have any type of review to ensure all candidates have been examined. The Presenter responded that the information may not be granular, but every program should have evidence to back up their claims on the attestations.

7. Public Comment: Ethical Analysis of Normothermic Regional Perfusion

The Committee heard a presentation on the OPTN Ethics Committee's white paper, *Ethical Analysis of Normothermic Regional Perfusion* and held discussion.

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:

The Committee discussed the paper and provided the following commentary, which was entered into official public comment:

The OPTN Patient Affairs Committee would like to thank the OPTN Ethics Committee for their thoughtful work in developing this proposal. PAC members are directly impacted by the decisions made during the procurement process. This is particularly true for the donor families on the Committee who have experienced firsthand the grief of losing a loved one and deciding to pass on their lifesaving gifts to strangers so they may live longer.

The Committee's concern regarding NRP begins with the donor families. When discussing donation with families, it is important to remember they are experiencing grief, trauma, and exhaustion. The discussion regarding NRP should be held at an appropriate time and in such a way that it does not burden the family. The families need to be reassured that everything was done to try to save the life of their loved one, and then informed on what NRP is and how it is not a lifesaving technique. Increasing the burden of information on families could increase the likelihood that authorization for donation will not be granted. There is already mistrust within certain communities when it comes to deceased organ donation, and if proper education on NRP does not occur then this process risks increasing that mistrust.

Some PAC members suggest including religious leaders in helping to develop the way this topic is introduced to donor families. The fact that it is stated that NRP "may violate the Dead Donor Rule" should make the system take pause. Risking public trust surrounding this issue could be detrimental to the transplant community. Clearer guidelines are needed to ensure that patients and families approached about organ donation know they can opt out of NRP. The conclusion to "proceed cautiously" is ambiguous and increases the ethical concerns many people will have about NRP. Will the use of NRP increase the number of utilized organs, and is there data to support this? If not, then we must seriously weigh the utility that NRP provides against the potential harm it can do to public trust in our transplant system.

8. Inactive Status Project Discussion

The Committee discussed a potential project regarding notification to candidates when they are made inactive on the waiting list. A member gave a brief presentation prior to the discussion.

Presentation summary:

A Committee member reviewed the project timeline, noting that today's discussion is about what data might be needed for the project, and to develop a research question. The Committee still needs to clearly diagnose the problem before sending the project to the Policy Oversight Committee for approval.

OPTN Policy 3.5, Patient Notification lists the times a patient must be notified by their transplant hospital. Those times are when the patient is registered on the waiting list, when the patient's evaluation for transplant is complete but the patient is not registered on the waiting list, and when the patient is removed from the waiting list for reasons other than death. A candidate being made inactive on the waiting list is not listed in policy for requiring notification. There was a proposal in 2014 to require such notification, but the proposal did not proceed past public comment. Additionally, there is no requirement in policy for centers to review their inactive list.

The member reviewed the waiting time policy for inactive candidates. Each organ has a different process for counting waiting time. Kidney, kidney-pancreas, lung, pancreas, and pancreas islet allow for waiting time to be counted while inactive. Heart does not factor waiting time into its allocation, and liver has waiting time as a low priority. Intestine allows for 30 days of inactive time to be counted. The member then reviewed the inactive reason codes with the Committee. The member reviewed the current waiting list numbers. As of September 10, 2023, there are a total of 58,608 patients active on the waiting list, and 44,725 inactive patients on the waiting list. For kidney specifically, there are 47,546 active patients on the waiting list, and 40,977 inactive patients on the waiting list.

The member then reminded the Committee that the OPTN currently does not collect the method used to notify a candidate they are inactive, the rate of candidate acknowledgement to becoming inactive, or when a candidate is made inactive due to an error. The member informed the Committee some of these could be included in the Committee's proposal.

In preparation for the data discussion, the member reviewed some data points the Committee could request. The committee could ask for the average length of time spent inactive, total number of times a candidate is made inactive after reactivation, and how long candidates spend active on the waiting list before becoming inactive. This could be broken down over a ten-year period and by race, gender, age, and inactive reason code. The member suggested looking at the impact of eGFR and reactivation, and the number of patients who are inactive at one center but made active at another.

The member ended the presentation by reviewing a few possible research questions:

- Do candidates in inactive status know they are inactive?
- Are there disparities based on factors like gender and ethnicity in terms of which candidates are made, inactive, how long candidates remain in inactive status, and the likelihood of returning to active status?

The member then shared a possible problem statement: Too many inactive candidates are not moving back to active, and not made aware of active or inactive status.

Summary of discussion:

Contractor Staff asked what the goal for the data request is, because if the goal of the project is about candidate notification then there is not a lot of data that would be helpful. Different data options exist for different projects. A member responded that the Committee does not know what it does not know, and they would like to see the data before making a determination on the scope of the project. A member suggested that perhaps inactive status is less of a problem than the Committee suspects if they can see how many candidates are never made inactive or why they are made inactive.

A member asked how difficult it would be to get all the data the Committee has asked about, because if they can get all of it that would be helpful but if some of it is impossible to get or extremely difficult it might be better to go with what is the easiest to obtain and start there. Contractor Staff pointed out that three data points are collected and can be obtained, and asked if that would that be sufficient to start discussing a data request. Another member of the Contractor Staff asked which of the data points would be most useful as the Committee pursues a project. A member responded that there are specific data points they feel would be helpful in developing a proposal regarding notification, but other points would be helpful if looking at moving candidates from inactive to active status.

A member stated that length of time inactive based on inactive reason code would be helpful. Having that data broken down by inactive reason code would be important for any project the Committee chooses to pursue. A Visiting Board Member agreed and suggested the committee look at time inactive by reason code as a starting point for a project, and notifying candidates when they become inactive could empower candidates to seek out ways to become active again. The Visiting Board Member warned that this could lead to multiple projects and recommended the Committee focus on one. A member responded that the Committee is not trying to develop a solution to a problem today, but at minimum they want to see candidates notified when they are made inactive. The member continued that they would not want the data they are requesting to narrow the focus down to only that one point because there may be additional parts the Committee could incorporate into a proposal. The member said they would want to know how long it would take to get the basic data points that had been discussed. Contractor Staff asked if one of their colleagues could elaborate. Another Contractor Staff member stated they could not give a timeline on how long it would take until the data request is approved and would also depend on the capacity of contractor staff, but some of the data is easier to obtain than other data points.

Contractor Staff explained that a data request would result in an analysis report for the Committee to review, but the raw data could be requested outside of the Committee without a report.

Contractor Staff asked the Committee if a breakdown of inactivation by code and time spent inactive would be a reasonable request to start, keeping in mind this does not have to be the only time the Committee requests data.

The Chair asked a member if they could re-examine the data points they want to request within a few weeks. The member agreed. The Chair said the Committee would move forward when that happens.

Upcoming Meeting

- October 17, 2023; virtual.

Attendance

- **Committee Members**
  - Garrett Erdle
  - Molly McCarthy
  - Andreas Price
  - Cathy Ramage
  - Calvin Henry
  - Cheri Coleman
  - Denise Abbey
  - John Sperzel
  - Julie Spear
  - Justin Wilkerson
  - Justine van der Pool
  - Kristen Ramsay
  - Lorrinda Gray-Davis
  - Sejal Patel
  - Steve Weitzen
  - Tonya Gomez
  - Wendy Leavitt
- **HRSA Representatives**
  - Arjun Naik
  - Daniel Thompson
  - Adrienne Goodrich
  - Frank Holloman
  - Jim Bowman
  - Julie Ross
  - Mesmin Germain
  - Suma Nair
- **SRTR Staff**
  - Allyson Hart
  - Katie Audette
- **UNOS Staff**
  - Alex Carmack
  - Desiree Tenenbaum
  - Cole Fox
  - Holly Sobczak
  - Kaitlin Swanner
  - Kayla Temple
  - Kelley Poff
  - Kelsi Lindblad
  - Kieran McMahon
  - Kim Uccellini
  - Krissy Laurie
  - Kristina Hogan
  - Laura Schmitt
  - Lindsay Larkin
  - Meghan McDermott

    - Rebecca Brookman
    - Rebecca Murdock
    - Roger Brown
    - Sally Aungier
    - Sara Moriarty
    - Sharon Shepherd
    - Tina Rhoades
- **Other Attendees**
    - Dianne LaPointe Rudow
    - Keren Ladin
    - Kyle Herber
    - Martha Pavlakis
    - Melissa McQueen
    - Nahel Elias
    - Scott Lindberg
    - Stevan Gonzalez
    - Valinda Jones