

**Health Resources and Services Administration (HRSA)  
Advisory Committee on Organ Transplantation (ACOT)**

**U.S. Department of Health and Human Services (HHS)**

Virtual Meeting, May 20, 2019

**ACOT Members**

*Voting Members*

David Mulligan, M.D., FACS (Chair); Nancy Blumenthal; Linda Cheatham; Jay Fishman, M.D.; Andrew Lee, M.D., FACS; Janice Whaley, MPH, CPTC, CTBS; Erroll Williams, RMP

*Non-voting (Ex Officio) Members*

Barbara Bartman, M.D.; Sridhar Basavaraju, M.D.; Nancy Bridges, M.D.; Scott Brubaker; Diane Corning, Esq.

*Executive Secretary*

Frank Holloman [for Robert Walsh]

*General Counsel Staff*

Laura Odwazny [for Emily Marcus Levine, J.D, and Rina Hakimian, J.D., M.P.H.]

**Welcome and Opening Remarks**

*David Mulligan, M.D., Vice-Chair, ACOT*

Dr. Mulligan opened the meeting 10:02 a.m. and asked committee members to introduce themselves.

**HRSA Division of Transplantation (DoT) Organ Transplantation Program Update**

*Frank Holloman, Acting Director, HRSA, DoT [for Robert Walsh]*

Mr. Holloman discussed the organization of HRSA's transplantation program, their organ donation outreach activities, efforts to increase organ donation awareness, and the reimbursement program of the current awardee, the National Living Donor Assistance Center (NLDAC). DoT, in HRSA's Healthcare Systems Bureau, is the primary Federal entity responsible for oversight of solid organ transplantation and for initiatives to increase the level of organ donation in the United States.

There are now more than 30 Organ Procurement and Transplantation Network (OPTN) committees, which operate under the authorization of the National Organ Transplant Act (NOTA; Public Law 98-105). In addition, the Scientific Registry of Transplant Recipients (SRTR) supports studies by conducting performance evaluations of solid organ transplantation in the United States for both patient and graft survival. The current contractor is the Minneapolis Medical Research Foundation Chronic Disease Research Group. The OPTN contractor provides administrative support, while the SRTR contractor provides the analytic components.

HRSA coordinates with other agencies, specifically the Centers for Medicare and Medicaid Services (CMS) on complementary oversight issues for transplant centers and organ procurement organizations; the Centers for Disease Control and Prevention (CDC) on issues related to transplant-related communicable disease transmission; the Food and Drug Administration (FDA) on FDA-regulated transplant products, such as organ perfusion devices and services; and the National Institutes of Health (NIH) on transplant research-related efforts, such as development of the HOPE Act research criteria and the National Transplant Cancer Match Study.

The number of transplantations is trending upward, from 34,770 in 2017 to 35,694 in 2018, but 113,727 prospective recipients remain on the waiting list. The overall goal of this grant program is to reduce the gap between the demand for organs and the supply of organs. To further this, they are identifying successful strategies that can serve as model interventions to increase registration for deceased donation; promote family discussion and knowledge about organ donation, including vascularized composite allograft (VCA); and increase awareness and knowledge about opportunities for and the risks and benefits associated with living donation.

NLDAC is funded via HRSA's Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation. It targets financial barriers to living donation, provides reimbursements to donors for donation-related travel and subsistence expenses, and operates under a cooperative agreement between HRSA and the University of Arizona. They are currently working on a demonstration project to counter the barrier presented by lost wages when donors must be out of work.

### **OPTN Update, including Organ Allocation Policy Changes**

*Craig Connors [for Brian Shepard, OPTN Executive Director], United Network for Organ Sharing (UNOS)*

The OPTN contract was renewed to take effect April 1, 2019, and run through 2023. New tasks include establishing an OPTN branding plan; forming new committees (operating, governance); improving collaboration; establishing application program interfaces (APIs), programs that allow data exchanges between different computer applications; refining regional studies, the mechanism for community feedback (e.g., they are embarking on a plan to evaluate the regulatory structure as to whether it is the best to deliver OPTN's goals); and devising innovative tasks.

Mr. Connors described OPTN's board and operating committees (including nominating, finance, policy oversight, data advisory, and professional standards). Each must deliver an annual report to the board of directors. OPTN's final rule on geography requires that allocation of cadaveric organs not be based on a candidate's place of residence or place of listing, except where required by sound medical judgment. Donation services areas (DSAs) are not good proxies for donor proximity. Therefore, HRSA instructed OPTN to replace DSA-based distribution with something more consistent with reality. Lung and heart transplantation distributions have transitioned. For VCA, kidney, and pancreas transplantation, OPTN members will meet in person at the end of June 2019 to draft a policy proposal for public comment in the fall. That policy will be considered for approval at the December 2019 board meeting. All 11 models were based on a hybrid approach (i.e., local and national distribution).

IT and data projects include APIs, DonorNet Mobile for transplant centers, and self-service data reports. A pilot project will filter offers according to the transplantation center's self-selected

criteria. Some centers may not be equipped or predisposed to accept certain organs, and it takes time to find appropriate receivers.

The next OPTN board of directors meeting will be held June 9–10 in Richmond, VA. Participants will review policies for heart and VCA geography, split liver, HOPE Act expansion, a multi-organ ethics paper, en bloc kidney clarification, and the definition of maintenance dialysis. Other discussions will include a systems performance update, kidney/pancreas geography preview, and the 2020 OPTN budget. Mr. Connors reminded everyone that they must work with HRSA to keep the website current ([optn.transplant.hrsa.gov](http://optn.transplant.hrsa.gov)).

## **INNOVATIVE ORGAN PROCUREMENT ORGANIZATION PRACTICES**

### **Organ Procurement Organization (OPO) Recovery Center Experience**

*Diane Brockmeier, Mid-America Transplant*

Current practice involves a traditional donor hospital, an organ recovery center housed at the OPO, partnerships with community hospitals, and partnerships with transplant centers. Ms. Brockmeier gave the advantages of the freestanding organ recovery center (ORC) model.

The ORC model has a state-of-the-art organ recovery facility; multiple 600-square-foot operating room (OR) suites to accommodate multiple teams; and a donor care unit (DCU), some with adjacent family rooms. Donors eligible for transfer are brain dead; there are no donor after cardiac death donors. Pediatric donor transfer practice varies by OPO due to equipment requirements.

The transfer process begins with a huddle with the hospital staff to establish a plan. OPO staff explain the transfer to family members during the authorization process, which allows the family ample time with the donor and ensures that the donor is clinically stable. Transfer is via ambulance with equipment and staff from the OPO. The recovery center organ donation process is based on the donor hospital relationship with OPO staff. It includes critical care transport, donor management (pharmacy, blood products, etc.), organ evaluation, and organ recovery surgery.

The OPO benefits donor families, donor hospital partners, transplant center partners, OPO staff, and transplant recipients. Moreover, time spent and donor costs have dropped significantly. The free-standing model frees up hospital resources, both material and staff, while transplant centers have consistent staffing and equipment and fewer delays.

To date, nine cities have adopted the free-standing model: Los Angeles, Denver, Dallas, New Orleans, Jackson, Ann Arbor, Cleveland, and Pittsburgh. However, the model requires a certain volume to support it.

Outcomes realized include:

- Increased yield of organs per donor
- Dedicated testing and strategies
- A transplantation center OR is optimized for organ recipients
- Safety risks are minimized because the donor is moved, and not multiple recovery teams
- Decreased cold ischemic time
- Cost savings
- Improved donor satisfaction

## **Organ Utilization Outside the DSA: Maximizing Organs Transplanted**

*Joe Ferreira, Nevada Donor Network*

The Nevada DSA consists of 2.2 million people within 84,183 square miles and experiences 17,227 deaths annually, the 46<sup>th</sup> highest in the nation. Organ donation and transplantation have grown. Currently, Nevada has 26 percent local kidney utilization and 11.5 percent total local organ utilization. To increase the number of donors and organs transplanted, Nevada is focusing on:

- Creating donor champions in trauma centers
- Building relationships in hospitals
- Relationships with regional and national transplantation centers
- Relentless pursuit of organ placement (they have expedited offers, including in Canada)
- Recovery surgeon model (private practice, multi-center coverage)
- Customer service driven culture (staffing model, OR time accommodation for organ recruitment)

## **TxJet**

*Steve Johnson, Indiana Donor Network*

The Indiana Donor Network realized that more lives could be saved if donated organs could travel safer and faster to a recipient. This would advance the donation process and the critical timing between recovery and transplantation and in the process increase the donor pool.

Since 2014, TxJet pilots have flown more than 2,000 organs to their recipients. In 2018, TxJet flew 495 flights. Transplantation will require air transport more and more.

## **Dedicated Local Recovery Surgeons: Operational Efficiencies and Consistencies Leading to More Organs Recovered and Transplanted**

*Lori Brigham, Washington Regional Transplant Community (WRTC)*

WRTC is a nonprofit organ procurement organization in the DC metro area of approximately 5.5 million people. It includes 45 hospitals and six transplant centers, and an in-house recovery surgeon. Having an OPO-designated recovery surgeon—someone who represents the OPO—in the OR improves care. This is someone to mediate, a medical director on site in real time.

Benefits include:

- Reduces surgical errors
- Provides a surgical presence in the OR who can act if issues arise
- Consistency in biopsy protocols
- Enhances OPO surgical capability for organ recovery for various research protocols
- Provides abdominal recovery of kidneys, liver, pancreata, and lungs if the center declines in OR or if the transplant center is unable to send a team
- Places kidneys on a pump when required
- Reduces time in the OR
- Medical director is also present to assist in training and instruction of fellows and others
- Donor hospital comfort level with organ recovery cases (i.e., there is increased trust and respect when the WRTC medical director is present)

- The OR case is posted under the medical director’s name rather than a fake surgeon’s name like “organ recovery” or a physician’s name on our behalf

## Discussion

*Mr. Mulligan* asked what strategies the Committee should recommend so transplant hospitals can identify donors and avoid the financial impact of donor recovery outside the hospital.

*Ms. Brockmeier* suggested that the Committee give their recommendation to CMS. This is not a regulatory issue, but the wording on CMS’s cost report. The easiest thing for CMS to do to bypass negative consequences would be to change wording on the cost center report where it asks where the organ was supplied. She will share specifics of what Mid-Atlantic Transplant has asked CMS to address.

*Dr. Fishman* asked about the upfront development costs for an organ procurement center. If those costs were passed along to the medical centers, it might create a hurdle. Also, what is the geography of a procurement center that works? *Ms. Brockmeier*: An example is an organ collected in Maine that routinely gets transported to Boston. Many hospitals already have suites for recovery of tissue donated, and organ recovery can be done in tandem with tissue recovery. Regardless, the returns must warrant the investment. But, for example, renal transplantation charges have not risen in 12 years.

*Dr. Lee*: What are the implications of transitioning out of the DSA model for patients in rural areas? *Mr. Connors* agreed that this is a complicated issue because of the different ways to measure medical urgency. In some rural areas, donors and recipients are disadvantaged. The goal of policies is to have equitable allocation so fewer people die awaiting transplantation. Models have been based on different DSA locations and all reports are published. Results indicate no significant disparities of rural vs urban recipients.

*Dr. Lee*: What about transplant centers located in less densely populated areas? *Mr. Connors*: Despite much discussion, we don’t know. All participants’ behavior has been changing over the years in ways that affect these issues. Allocation is the best it can be at present, but eventually continuous distribution will be the model.

*Dr. Mulligan* asked *Mr. Ferreira* about the problems of increasing the number of recovery centers. *Mr. Ferreira*: With minimal transplant activity in the area, Nevada had trouble finding recovery surgeons. But, they did find a group in Arizona that covers multiple transplant centers and it added recovery services for Nevada. Many unanticipated benefits resulted, including helping to find homes for organs they had trouble placing.

*Ms. Cheatham* noted that 70 percent of lungs in the WRTC area were transported elsewhere last year. *Ms. Brigham* said that is a reflection of need (e.g., NOVA transplanted many lungs last year, but still exported many). *Ms. Cheatham*: Some places just aren’t doing well enough getting organs for many reasons. Could the number of organs recovered account for it? *Ms. Brigham* said you have to look at the discard rate as well as export rate—there may be high turn-down in the OR. There are many reasons why organs are not utilized.

*Mr. Connors* replied to *Ms. Whaley*: OPTN is involving OPO groups to work on organ placement. Even if the number of organs increases, it will be a challenge to make sure the organs are transplanted and not discarded because of the time issue. All have an OPO perspective when considering adoption of policies. Being sure gifted organs are used is one of the goals, but utilization of organs is driven by behavior of the whole system and not just policy.

*Ms. Whaley* worries about geographic disparities. She asked if it is too early to see a difference in recipient outcome as the DSA model is being dropped and if disparate wait lists affect mortality. *Mr. Connors*: Lung is the only organ for which we have substantial evidence. Indications are that sicker people are getting transplants more quickly. Nevertheless, there are unintended consequences of taking organs in less populated regions. Our goal is to have fewer people die waiting for organs.

*Ms. Blumenthal* wondered whether telemedicine is being used. *Ms. Brigham* replied that it is. They want to encourage a situation where the team does not travel, so, for example, they up-load all bronchial images to donor networks. *Dr. Mulligan* noted that we are on the cusp of transition using IT for more efficiency and ability to transplant more organs.

*Dr. Mulligan* asked whether Mr. Johnson foresaw a time when existing flights would not suffice. *Mr. Johnson*: Because no one can ensure even distribution, TxJet must use third-party charters sometimes. TxJet's goal is to keep third-party charter flights under 5 percent. But, they ensure extreme and accurate vetting of that third party, making sure they understand the value of the organ and the importance of time. One challenge is that the volume from transplant centers is rising. Pilot shortage is a nationwide phenomenon and that will continue to be a challenge. TxJet grows as it needs to keep that number in the 5 percent range. In addition, TxJet is sometimes used to import or export an organ recovered by someone else.

*Ms. Brigham* said they have been filling the need for additional trained and experienced recovery surgeons with some local transplant surgeons used for back-up. One problem is that CMS hasn't raised the reimbursement rate for nephrectomy surgeons in 35 years. She wants to find models that will work.

### **Proposed Expansion of Living Donor Reimbursement**

*Akinlolu O. Ojo, M.D., Ph.D., NLDAC Staff Program Director, Associate Vice President for Clinical Research and Global Health Initiatives, University of Arizona Health Sciences, Tucson, AZ*

*Robert M. Merion, M.D., FACS, NLDAC Deputy Director, President, Arbor Research Collaborative for Health, Ann Arbor, MI*

*Amit Mathur, MD, MS, NLDAC Program Evaluation Specialist, Assistant Professor of Surgery, Division of Transplant Surgery at Mayo Clinic, Phoenix, AZ*

*Dr. Merion*: The number of deceased organ donors continues to rise, but the number of living donors peaked several years ago and has not increased. Meanwhile, the number of prospective recipients steadily increases. Evaluation for living organ donation is costly and those medical costs are generally borne by the intended recipient's insurance. Direct out-of-pocket costs for travel, lodging, food, etc., are usually not covered by the donor's or the recipient's insurance. In addition, lost wages are not reimbursed. Although a few programs can help, many potential donors who are otherwise willing do not come forward because of personal financial disincentives.

There are no medical benefits for being a donor, but other benefits include the psychological benefit and emotional satisfaction of helping a loved one; reducing pressure on the deceased donor system; increasing the ability for more people to transition from dialysis to transplant, which saves lives and money; and the fact that living donor transplants function longer than deceased donor transplants, reducing the need for repeat transplantation. On the other hand, the

risks of living donation include minor and major complications related to surgery; altered body image and scarring; death, though rare it can occur (~3 in 10,000); very small excess risk of kidney failure in the long term, but not zero; and time off work with consequent lost wages.

HRSA issued a request for living organ donors, which was awarded three times and has been renewed to continue the program from September 2019 to the end of August 2024. The program is regulated by the National Organ Transplantation Act and the Organ Donation Recovery and Improvement Act, which authorizes grants for living donor travel, using government reimbursement as the last resort. Donor and recipient eligibility is 300 percent of the Federal poverty guideline (FPG). Median income for the 2018 program was less than \$32,000 for recipients and about \$47,000 for donors. Allowed reimbursement for travel, meals, lodging, and incidentals can be as much as \$6,000.

Controlled value cards can be used for pre-imbursement. These cards are underused and have been shown to be virtually never misused. There are about 120 participants/users at any time. Nationally, 10 percent of living donors are part of NLDAC. Between 2007 and February 2019, NLDAC received fewer than 10,000 applications, which have had an 87 percent approval rate. Seventeen million dollars were paid out for donor travel. NLDAC has completed 4,900 donor surgeries, 75 percent of whom say they could not have donated without NLDAC support. Therefore, without the program, 3,675 fewer transplants would have occurred since 2007.

The alternative to transplantation is dialysis, which costs \$81,485 per year vs. \$30,101 per year for transplantation. Over 5 years, there is a 15-fold to 34-fold savings. NLDAC's vision is to expand eligibility to 500 percent FPG, waive income verification for donors who need less than \$500, approve applications from non-directed donors, and reimburse child care and elder care expenses (two-thirds of living donors are female, so 30 to 50 percent incur these expenses after living donation). In addition, we suggest that all recipients and donors be given NLDAC information. About half of potential donors become actual donors, but it is hard to predict the number of applicants who did not apply because of expenses.

## **Discussion**

*Ms. Cheatham:* If possible donors must refuse because of the expense, can they get money elsewhere? *Dr. Merion:* Information on possible sources is made available to them. Some people do fundraising or other ways to enable them to donate. Other considerations are the time the graft will function and the time before they need another transplant. If they do not need another transplant, those dollars will be available to someone else. Medicare does not fund this program, but its sister agency does. Reimbursement for lost wages and travel savings of insurance agencies—make it a “no brainer.”

*Mr. Williams* hopes people utilize the services. He donated for his brother. In the last hours, the doctors decided he and his brother were not a good match, so they had to go from Nashville (where they had no overhead) to Jacksonville. However, they were able to stay in an unused part of the Jacksonville hospital and they befriended cafeteria staff who gave them food. Without that it would have been much more costly. *Dr. Mulligan* thought the case for reimbursement could not be made any more eloquently than this. In this instance, the family pulled out all the stops to make it happen, and it was still difficult. People who do not have those family resources cannot do it at all.

## **INNOVATIVE PRACTICES IN ORGAN DONATION AND TRANSPLANTATION**

### **National Kidney Foundation Consensus Conference to Reduce Kidney Discards**

*Matthew Cooper, M.D., MedStar Georgetown Transplant Institute; ACOT Chair*

*Tonya Saffer, M.P.H., Vice President for Health Policy, National Kidney Foundation*

*Dr. Cooper:* The incidence of end-stage renal disease continues to increase to epidemic proportions. Yet, many people never make the list of potential kidney recipients because they die or become too sick to undergo surgery. The wait has grown to 8 to 10 years, but at the same time the rate of deceased donor kidney discards has also increased.

When the new kidney allocation system was instituted in 2014, about 19 percent of all retrieved kidneys were discarded. The National Kidney Foundation Consensus Conference to Decrease Kidney Discards, was held May 18–19, 2017. Its working groups were: Donor Evaluation and Procurement, Recipient Selection and Allocation, and Education and Research. Their goal was to find ways to reduce demand for kidney transplants and dialysis, to increase the supply of kidneys available for transplant, and to address wait-list management and priorities for use.

Specific recommendations were:

- In public/private partnership, develop a learning action network of OPOs, transplant programs, nephrologists, and patients to identify best practices in maximizing the use of donated kidneys, including imperfect ones.
- Modify the Hospital Inpatient Prospective Payment System Diagnosis-Related Grouping for organ transplants to allow for adjustments to payment for transplanting higher-risk kidneys.
- Change transplant program metrics used by OPTN. Remove “high-risk” kidneys from the 1-year graft survival metric and develop a patient quality-of-life metric 1-year post-graft survival.
- OPTN should require transplant programs to inform patients of high-risk kidney offers and afford them the opportunity to participate in shared decision-making regarding acceptance or decline of the offer.
- OPTN should identify transplant programs that never or very rarely accept high-risk kidneys and make changes to the kidney allocation policy to allow OPOs to direct donations of high-risk kidneys to programs that are most likely to use them.
- OPTN should also modify the kidney allocation policy to require each OPO to have at least three back-up transplant programs ready to accept a kidney if the first program declines.
- Develop a standardized process that all transplant programs and donor hospitals must follow to determine their interest in an organ offer to accelerate the time the kidney is out of the body and in cold storage.
- NIH should fund a randomized trial of renal biopsy use in organ procurement and acceptance to understand the role of kidney biopsies in the evaluation of organ quality and the impact of that on allocation and acceptance.

*Ms. Saffer* presented the “Blueprint for the Secretary on Kidney Health Policy and Transplantation.” Specific recommendations are intended to reduce discards:

- There should be a public/private partnership to develop a learning environment. Discussion among OPOs, transplant programs, et al., should continue.
- Modify hospital inpatient prospective payment system diagnosis-related grouping for organ transplants to allow for adjustments to payment for transplanting higher-risk kidneys.
- Remove high-risk kidneys from the 1-year evaluation and add a quality-of-life evaluation over the short and long term.
- Require programs to inform patients about high-risk kidneys regarding acceptance or decline of the offer. Now, patients are not involved in the decision-making. Decisions made are considered best for the patient at that time, but the program must be patient centered.
- Modify allocation policy to have at least three back-up transplant programs ready to accept the kidney if the first program declines.

*Dr. Cooper* added that some data currently exist and that it is important to recognize that certain kinds of transplants will never be used. We need to define what organ can be used in what hospital system so we can get the organ to where it will be used. Another problem is that few data demonstrate that long-term outcome can be determined from biopsy, yet biopsy is now used to determine whether or not to use an organ. And, we need to follow those transplants over time. *Ms. Saffer* noted the pilot trial in St. Louis.

## **Discussion**

*Ms. Saffer* replied to *Dr. Mulligan* that this group could be helpful with recommendations for OPN. *Dr. Cooper* hopes ACOT will discuss with CMS opportunities to keep the conversation going. Both organizations want to increase the number of transplants and decrease the number of discards. *Ms. Saffer* said that was modeled from a previous breakthrough.

*Ms. Cheatham* saw that this does not relate just to kidneys but to all organs.

*Dr. Mulligan* asked the group to think about the specific verbiage to frame recommendations at 3:30 p.m.

## **Innovation in Organ Transplantation Meeting Report**

*Melissa Greenwald, M.D., MA Greenwald Consulting*

The aim of the Innovation in Organ Transplantation Meeting was to address opportunities for structural, regulatory, and policy changes to facilitate innovation in the field of organ transplantation. For this we must understand data flow, transplant systems, and how outcomes metrics are measured.

Three topic areas became apparent and participants split into subgroups focusing on the transplant system they want and not the one they have. The groups were:

1. Coordination of policy and oversight activities so recommendations can be presented as a single voice.
2. Data use in evaluating performance. It is unclear whether current performance measures are the best ones for today's transplantation community.
3. Components for redesign that aligns with our goals.

Specific consideration must be given to outcomes data in the context of innovative research. There is a perception that innovative research is more risky and therefore places the funding of a transplant center at risk for losing Federal money. To counteract this, a national review panel could be included to assess proposed studies using standardized criteria targeting the degree of innovation and the potential risk.

Factors for use and criteria development should include:

- Institutional review board-approved studies
- Studies considered innovative with potential significant impact on clinical practice
- Studies should contribute to the Institute for Healthcare Improvement triple aims of improved patient clinical outcomes, improved health of the transplant population, and cost efficiency
- Limited number of patients
- Use centers with excellent prior performance metrics
- Studies carrying an FDA investigational device exemption or investigational new drug application (possibly FDA phase 1 or 2 trials)
- Use of organs that would otherwise be discarded

The major finding of the workshop was the need for a formal governmental interagency working group (i.e., the Innovation in Transplantation Working Group) to coordinate transplant-related activities in close collaboration with patients, transplantation experts, and other external stakeholders. Specifically, the group would do the following:

1. Develop a roadmap for policy and research in organ transplantation, co-sponsored by Federal and nongovernmental stakeholders.
2. Examine how best to assess and report clinical outcomes metrics in the context of innovative research.
3. Define how metrics for innovative research are used by the OPTN and CMS for reporting of transplantation outcome measures.
4. Create a mechanism to identify and facilitate innovative research that crosses traditional boundaries within transplantation.
5. Harmonize performance metrics among OPOs, clinical transplant centers, and other stakeholders (e.g., third-party payers).

Findings of the meeting held in autumn 2016 remain relevant. Namely, patients need a stronger voice and deserve new strategies to manage end-stage organ failure. Transplantation already is a positive model of nongovernment and government collaboration in policy development. The level of coordination required to manage policy development within multiple government agencies requires a high-level champion. Finally, we need to extend this model to develop an overarching strategy for the entire field of transplantation.

### **OPTN ad hoc Systems Performance Forum (SPC) and OPTN Collaborative Innovation and Improvement Network Updates**

*Chelsea Haynes and Henri Haskell, UNOS*

*Ms. Haynes:* Then-board-president Yolanda Becker founded the ad hoc SPC because the board recognized the need for common standards of system performance—not just components of the

system. Specifically, SPC will consider metrics and elements that could be universally accepted as performance standards for OPOs, transplant programs, and the system as a whole, and will identify ways OPTN could help drive system performance.

SPC is composed of 60 community members, 32 transplant professionals, 20 OPO professionals, 3 patients and donor affairs representatives, 2 HRSA representatives, and 2 SRTR representatives. The group consumed 3,020 staff hours and generated 115 ideas. They divided into three subgroups: Research Tools, Collaborative Improvement and Relationship Management, and Membership and Professional Standards Committee (MPSC) monitoring/measurement enhancements.

The charge was to engage in a strategic, community-driven, interdisciplinary conversation to determine how to best improve transplant system performance as a community; to identify what tools can be used to foster collaborative improvement; and to recommend next steps in the development of new or existing tools and strategies.

With a focus on identifying areas of consensus and priorities, the main topics are: research tools (dashboard, enhanced research and IT tools, organ recovery and transport), collaborative improvement and relationship management, and MPSC monitoring and measurement enhancements (OPO balanced scorecard and transplant balanced scorecard). Beyond the OPTN, the aims are a coordinated national transportation system, payment models and financial paradigm, partnership and advocacy, expanded OPTN scope, and recommendations to external stakeholders. Now the work is to catalog key actionable recommendations, identify potential applicable measures for driving system performance, and prioritize the most impactful actions.

A 2-day SPC meeting in Chicago with 110 committee members, public, staff, and government attendees concluded with the following themes:

- Data transparency and sharing is key to benchmarking for self-improvement.
- Increased collaboration, relationships, and standardization of practices will support system performance.
- Performance relies on members acting as good stewards.

In addition, SPC developed a series of recommendations for a report to the OPTN board of directors (e.g., metrics for self-monitoring and benchmarking, predictive analytics, offer refusal reasons, performance monitoring enhancements, and potential collaborative improvement efforts).

Recommendations for self-monitoring dashboards were total referrals by vent status, authorization rate; conversion rates, donor management goals prior to allocation, and transplant yield. Recommendations for transplant programs were number of late turn-downs or declines, speed from offer to acceptance or decline, relative rate of accepting organs (“rescues”), and rate of allowance of other teams to procure organs.

The report will be delivered to the OPTN board in June. Then the board can begin setting strategic project priorities and sharing conversation with the community.

*Ms. Haskell:* The first OPTN Collaborative Improvement Project (COIIN) was a 3-year HRSA-funded project using the collaborative improvement framework modeled after the Institute of Healthcare Improvement framework. Objectives are to review key learnings and to share how insights will support future OPTN Collaborative initiatives. COIIN used data sharing through

balanced scorecard of measures (SRTR cumulative sum reports). By identifying top performers, they compiled two cohort groups of hospitals to study from October 2016 to June 2018. Then they identified processes and developed intervention guidelines. Data sharing is key. They focused on wait-list management and organ offer acceptance and management. Key learnings and interventions to be shared include: providing the structure so the staff will work on their process to improve, peer coaching, data transparency, improvement in guidance and tools, and understanding the current state of a process to identify gaps and waste in the process.

Future innovations include virtual technology (videoconferencing and use of whiteboard technology), enhanced virtual collaboration space, data transparency and tracking, intake of ideas for discovery projects (portal), and research design for collaborative improvement design.

Next will be the National Deployment of Key Interventions from Kidney (KDPI Utilization) COIIN project, start-up of discovery projects, continued learning and sharing, and acceleration of improvement.

## **Discussion**

*Ms. Whaley* commended the work done to identify the top refusal reasons. *Ms. Haynes* thought many of these ideas could become recommendations and policy, but encouraged waiting for publication of the report. *Ms. Haskell*: HRSA approval is expected 80 days after submission (i.e., 4 to 5 months from implementation of the plan).

*Dr. Fishman* stated that proposals are important opportunities to increase organ utilization, but he is not hearing about innovations across silos (e.g., metrics that track an organ from a donor to the composite endpoint). We need to set priorities that span silos. Do any programs meet that need? *Dr. Cooper*: That was the greatest challenge we had, so that is where the work now begins. There is still a lot of work to be done.

*Ms. Cheatham* observed a huge gap—increasing the donor base. *Dr. Mulligan*: Many of these presentations did focus on increasing the number of organ donors in several ways (i.e., getting more living donors, using new strategies to identify potential donors, and studying the data we already have). But we did not talk about things like marketing. *Dr. Greenwald* has not focused on that, but was trying to solve the larger issues of coordination. *Ms. Whaley*: It will take collaboration of multiple efforts to increase donations. There are several OPOs and we need to hear what they are doing and how they are doing it and to encourage them to increase donations. It is a matter of getting back to basics and looking at what we as OPOs can do.

## **Public Comments**

***Joseph Hillenburg***: As the father of a heart transplant recipient who also has a rare blood type, he would need about 3 weeks of time off, but he is also the primary wage earner. Some funds are available, but not enough. Why not enable NLDAC to find ways to do this?

***Mary Faith Harty*** [read by Dr. Mulligan]: Ms. Harty had several concerns including:

- Cut wait-time for people who need a kidney transplant.
- One of the largest costs to Medicare is dialysis, and transplant is less expensive.
- Clarify the informed consent in regard to transmittable diseases such as cytomegalovirus, HIV, or hepatitis.
- Cut the 30 percent mismatch rate.

- Cut the discard rate. Between mismatch and discard, about one third of received kidneys are improperly transplanted.
- Ensure compliance for what is consented to.
- OPO must keep their computer system updated (as UNOS has not).
- Kidneys that become available because of the opioid epidemic make notice via the Uniformed Anatomical Gift Act (Winter 2018) a relevant topic.

*Dr. Mulligan:* UNOS has been upgrading their technology. *Ms. Cheatham* agreed with the comments about moving forward, being innovative, and not clinging to a legacy system. She joined ACOT in 2016 and this is the first time since then that the Committee has convened. She thought face-to-face meetings would be more productive than virtual meetings. The Committee must consider specific discussions based on input from the public.

*Mr. Holloman* noted that, because IT services are available for a specific time, the Committee must close the public comment session and move on to recommendations. People who want to comment but didn't have time should send their comments to him and they will be included in the meeting summary. Those comments follow:

***Thomas Kelly:*** In 2014, Mr. Kelly became a non-directed living kidney donor through the National Kidney Registry at the University of California–San Francisco. When he donated, his caregiver had to travel for his surgery and lost a week of income. While Mr. Kelly could overcome these hurdles, many potential donors cannot. He strongly supports immediately raising the NLDAC income thresholds to support more living donors and to reimburse lost wages and other expenses.

***Dilip Moonka, M.D.,*** Medical Director of Liver Transplantation, Henry Ford Health System, felt compelled to comment after seeing some fairly derogatory comments leveled against transplant professionals and programs by those who favor and may benefit from the “acuity circle” model.<sup>1</sup> DSA performance data are difficult to obtain, but what data there are suggest that donation rates and DSA performance are not the drivers of longer waiting times.

Residents of New York State have the lowest rate of signing up for organ donation and families of brain-dead patients have low rates of donating when approached. To complete the trifecta, New York hospitals do a poor job of identifying potential donor candidates. Meanwhile, a nearby DSA—Gift of Life in New Jersey and Philadelphia—does an outstanding job of organ procurement. The discrepancy between the two DSAs is not an “accident of geography.” It is a result of very succinct policy decisions, strategies, and commitment of resources. One of the largest shifts in organs in the acuity circle model would be from the Philadelphia region to the New York metropolitan region. This has to be considered a spectacular injustice squared. To paraphrase Lyndon Johnson, New Yorkers ought not be taking livers from Philadelphians that Philadelphians need and that New Yorkers could easily provide for themselves. That a New York transplant surgeon would accuse centers that will lose organs of being concerned about “profitability” is, at a minimum, an impressive display of irony (<https://www.npr.org/sections/health-shots/2019/05/14/723371270/new-liver-donation-system-takes-effect-despite-ongoing-lawsuit>).

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<sup>1</sup> In December 2018, the UNOS Board of Directors approved the “acuity circle” liver allocation policy, which replaces fixed, irregular local and regional geographic boundaries historically used to match liver candidates based on the donor location. Now it prioritizes the sickest adult liver patients using offers from deceased donors aged 18 to 69.

A second issue is the notion that the new system will save lives. The same supercomputers that are not able to give us DSA data advise us that the new allocation system will allow approximately 100 more transplants a year, but 8,250 livers allow for 8,250 transplants. This assumes that patients who are minimally ill are not getting organs that could be widely used. However, that should not be the case.

One final disappointment is that compromise plans that were not as drastic and that had broader support were discarded. Dr. Moonka's suggestion, based on his group's data, is that with the use of the model for end-stage liver disease–sodium (MELD-Na) score, the score at which patients clearly do better with transplantation than remaining on dialysis, has shifted from a MELD-Na score of 15 to a MELD-Na of 21 (Nagai et al., 2018, *Gastroenterology*). Data suggest that using the Share 20 or Share 21 policy would allow broader sharing of organs without affecting wait-list mortality and without the more complex and divisive changes of the acuity circle model. The OPTN/UNOS Liver and Intestine Committee has acknowledged the proposal but is waiting to see what happens with current allocation changes.

**Will Chapman** had three questions:

1. What considerations are being given for cost and logistics in broader sharing plans? The current acuity circle proposal will introduce substantially increased air travel with significantly increased complexity for OPOs with teams crossing in the air for the same recipient patients, and likely, increased discards and worsened organ utilization. In all other fields of healthcare, cost and logistics are strongly considered. There is simply no reason to increase the cost of organ transplantation while decreasing the number of transplants.
2. The proposed National Liver Review Board (NLRB) exception point scoring was not designed for the acuity circle plan and introduces severe problems that do not appear to be receiving attention. Specifically, we have never assigned different exception scores for the same condition within the same organ-sharing area. Yet under the current plan, patients in New York will receive higher exception scores for hepatocellular carcinoma than patients within the same 500-nautical-mile acuity sharing circle in Connecticut (and much of the Northeast). The major reason for this is that the way exception scores are calculated includes 12 months of trailing data based on prior transplants performed throughout a 250-nautical-mile circle around the transplant center, so transplant candidates at centers in regions that are more liberal with granting exceptions are significantly advantaged over other candidates. (And UNOS has previously recognized that certain regions approved as few as 75 percent of exception requests while others approved more than 90 percent of such requests.) UNOS went through a public comment period over this issue when the NLRB exception score was based on the median MELD within DSAs and leveled the scores for 4 of 58 DSAs several months ago, yet it has refused to address the issue for acuity circles. This is not a minor issue, since one-fourth to one-third of liver transplants occur in patients with exception point scoring. Furthermore, this will take years to correct.
3. The call for nominations to the ACOT published in the *Federal Register* in 2014 and available on the ACOT website states that, "Members shall not serve while they are also serving on the OPTN Board of Directors." Does ACOT plan to hold a transparent process to identify a new chair since David Mulligan will be the OPTN President and will serve on the Board effective July 1? The distinction between ACOT and OPTN is critical to allow the ACOT to provide independent advice to the Secretary.

**Melody Hicks:** Ms. Hicks adamantly supports NLDAC in raising the income cap and reimbursing lost wages and other expenses. She donated her right kidney to a dear friend on

January 29, 2019. It was a life-changing and humbling experience. Raising the income cap and reimbursing lost wages and other expenses will allow so many others to freely donate kidneys to loved ones or strangers in need. Many people are hesitant to become living donors because of the financial implications involved by being out of work and/or needing to travel. Willing donors should not have to face financial turmoil in order to save a life.

More than 100,000 Americans are currently waiting for organs, roughly 80 percent of whom await a kidney. Receiving a kidney from a living donor increases survival rates for the recipient. However, from 2008 to 2016, living kidney donation has decreased. Expanding NLDAC coverage to raise the income cap and reimburse lost wages and other expenses will help increase donation.

**Ned Brooks** is a non-directed kidney donor and founder of Donor to Donor, an organization dedicated to spreading awareness of the kidney crisis in this country and educating potential donors on how to donate most effectively. In the 3 years Donor to Donor has been active, they have counseled many prospective donors and have facilitated many living donor transplants. It is a loss beyond measure to have a potential donor decline to proceed because she or he cannot afford the time off work or the cost of transportation and other out-of-pocket expenses. A non-directed donor starts a chain of donations that may be three, five, or more transplants long. When we lose one of those donors because they cannot afford to donate, the financial cost to Medicare is in the many hundreds of thousands. The cost to all those families whose loved one has to stay in the living hell of dialysis as a result of that lost donor is incalculable. Research shows that increased support for living donation by removing financial disincentives has increased living donation in the United States and abroad. Please expand the NLDAC coverage so that we will not continue to lose these most valuable donors.

**Carol Offen**, a living donor in North Carolina, donated her kidney 13 years ago to her then 26-year-old son. They lived close to one another and the University of North Carolina transplant center. Ms. Offen was lucky to have a smooth recovery, so she might have gone back to her sedentary job in 2 to 3 weeks. But, as a family member of the recipient and a caregiver she could not. Furthermore, her son needed emergency surgery a week after his transplant. His recovery was slow and he stayed with his parents for about 2 months. Ms. Offen was lucky enough to have a supportive supervisor, access to short-term disability insurance, and an employer with a shared leave policy that enabled colleagues to donate their extra leave time to her. With NLDAC's proposed expanded coverage, she would not have needed to rely on leave donations. Few potential living donors have such luxuries. More than half the people on transplant wait lists are minorities, and many of their families and friends have the double disadvantage of an increased risk of kidney disease and often far less ability to ride out periods of missed pay.

NLDAC's policy of providing travel and lodging expenses for donors has been invaluable in enabling people to donate, many of whom would not have been able to do so otherwise. The prospect of lost pay affects even more potential donors than travel issues do. After her son had spent nearly 2 years on dialysis, he would have faced an additional 5 years or more tethered to a machine three times a week, draining his energy, his time, and his spirit. (Incidentally, the 5-year survival rate on dialysis is little more than a third.) Ms. Offen implored the Committee to help someone else's son avoid that long, dangerous wait for a donor by raising the income cap and extending benefits to cover lost wages.

**Mike Sosna**, a transplant recipient and volunteer, is the Director of Communications and Policy at Long Island Transplant Recipients International Organization (TRIO) (<http://www.litrio.org/>). This is a close-knit transplant support group of more than 100 transplant recipients and living donors in the Long Island area. TRIO volunteers and members are transplant candidates, transplant recipients, living donors, and donor families. Mr. Sosna expressed his and Long Island TRIO's strong support for expansion of NLDAC coverage to reimburse living organ donor lost wages and other expenses. Currently, while poor people are more likely to need transplants, wealthier people are likely to be donors. This is partly because our system forces donors to spend an average of \$4,000 each to save someone's life. This is unfair and he trusts that a way will be found to support this necessary change.

**Malay Shah, M.D.**, University of Kentucky; **Alan Reed, M.D.**, University of Iowa; **Christopher Sonnday, M.D.**, Michigan Medicine; **Jonathan Fridell, M.D.**, Indiana University Health; **Susan Orloff, M.D.**, Oregon Health & Science University; **Harrison Pollinger, D.O.**, Piedmont Transplant Institute; **Sean Kumer, M.D.**, The University of Kansas Health System; **Marlon Levy, M.D.**, Virginia Commonwealth University Health System; **Seth Karp, M.D.**, Vanderbilt University Medical Center; **Atsushi Yoshida, M.D.**, Henry Ford Health System; **Gene Ridolfi, MHA, RN**, Barnes-Jewish Hospital Transplant Center: The agenda for the May 20, 2019 ACOT meeting (the first meeting on the website since November 22, 2016) includes an update from OPTN regarding organ allocation policy changes (from Brian Shepard, CEO of UNOS) as well as a presentation on organ allocation outside of DSAs (from Joe Ferreira, CEO of Nevada Donor Network).

The website does not include a copy of Mr. Ferreira's presentation, but Mr. Shepard's slides include a quotation from Section 121.8 of the Final Rule as well as a slide entitled "Transition from DSA-based distribution." Based on the limited information available, it is difficult to predict exactly what the Committee will be discussing and how best to comment, but nonetheless we submit the following for your consideration.

Section 121.8 states that organ allocation policies shall not be based on the candidate's place of residence or place of listing, except to the extent required by preceding paragraphs in that section, including those that require organ allocation policies to be based on sound medical judgment, achieve the best use of donated organs, and be designed to avoid organ wastage and to promote patient access to transplantation.

We strongly urge ACOT to consider all aspects of Section 121.8, as well as Section 121.4, which specifically requires OPTN to reform allocation policies based on assessment of their cumulative effect on socioeconomic inequities. Unfortunately, there are severe disparities in health care access across our country, including access to the transplant waitlist, and those inequities must be considered when revising allocation policies. For those on the wait list, numerous research studies in liver allocation (including UNOS's own data) demonstrate that patients who live in remote areas farther from transplant centers die with lower MELD scores than those patients who live in more urban areas. This fact must be considered in determining the best way to allocate donated livers. Evaluating disparities based solely on median MELD at transplant, as OPTN has done recently, is deficient and yields misleading results.

When ACOT advises Secretary Azar or HRSA regarding changes to organ allocation, ACOT must carefully consider all policy options in a nonpartisan way so that the best outcome for patients may be achieved. Such consideration must comply with all regulatory procedures and

allow for a full, public debate of the issues, not one that is limited to those who are familiar with OPTN, since the majority of the public, many of whom have agreed on their drivers' licenses to be organ donors, are not privy to that organization's operations.

ACOT may also wish to know that OPTN's most recently proposed liver allocation policy, the Acuity Circles Policy, in conjunction with the NLRB as modified to fit that policy, will most certainly result in fewer liver transplants performed nationally (based on SRTR models) as well as a candidate's place of listing affecting his or her likelihood of receiving an organ offer. OPTN has structured exception points under the NLRB to be assigned based on the median MELD at transplant within a 250-nautical-mile circle of the listing transplant center.

OPTN has calculated this median score for each transplant center ([https://optn.transplant.hrsa.gov/media/2844/mts\\_distribution.pdf](https://optn.transplant.hrsa.gov/media/2844/mts_distribution.pdf)) and exception patients listed at any given center will be assigned a MELD score of the center's median score minus three.

Therefore, two exception patients with identical lab results and identical clinical presentation could have two very different MELD scores depending on where they are listed, from a low of 23 to a high of 31 (excluding Puerto Rico). Under the Acuity Circles Policy, the patient with a MELD score of 31 will be much more likely to receive an organ than the patient with a MELD score of 23, despite identical clinical characteristics. This is the very definition of basing organ allocation on a candidate's place of listing.

Finally, we note that the ACOT charter describes the Committee's duties as advising the Secretary on efforts to maximize the number of deceased donor organs available for transplant. Obviously, some organ procurement organizations have significantly underperformed in recent years. UNOS's own data shows that bringing New York donation up to a par with Philadelphia's would add over 200 livers per year for transplantation. However, in lieu of local improvement, New York centers ask all Americans to spend millions of dollars to pull organs into New York from a nearly 600-mile arc around their State. The substitution of external acquisition in place of genuine improvement from within is a failure of the system. Instead of wasting millions of dollars flying organs around the country (and simultaneously hurting rural Americans), why not invest those millions in improving donation rates in parts of the country where donation is indefensibly low? Those dollars would then result in more organ transplants and more saved lives, rather than just shifting and wasting the existing limited resources.

Ultimately, the highest priority of all physicians is to "do no harm," and that principle should be incorporated in organ allocation policymaking. Organs should not be removed from regions where deaths are greater and distributed to areas where death is less likely. Likewise, allocation policies supported by ACOT, HRSA, and OPTN should not decrease the number of transplants performed nationally. If the ACOT has further need for specific information, we would be happy to provide it.

### **Comments Submitted Before the Meeting**

The *National Kidney Foundation* recommends:

1. CMS should adjust the risk determination for diagnosis-related group codes for kidney transplantation as part of the inpatient prospective payment system to account for the additional cost of transplanting high kidney-donor-profile-index kidneys donated after cardiac death, or otherwise considered high-risk for transplantation to account for the increased costs incurred by programs in the use of these kidneys.

2. Eliminate the high risk for discard organs from the Scientific Registry of Transplant Recipients (SRTR)-reported metrics in current Program Specific Reports to encourage innovation and decrease risk aversion in the transplantation of these organs.
3. Develop and implement a patient quality-of-life metric 1-year post-graft survival to report through SRTR.
4. Recommend that transplant programs be required to inform patients of high-risk kidney offers and afford them the opportunity to participate in shared decision-making regarding acceptance or decline of the offer.
5. Facilitate, through grant-making or other opportunities, the development and dissemination of shared decision-making tools for patients and transplant programs, in conjunction with community partners.
6. Support an alternative allocation system that, once a high risk for discard organ is identified based upon known donor characteristic, these organs will only be offered to transplant programs that have a history of both accepting and transplanting these organs. Ensure that patients are also aware of programs that do not accept high-risk offers.
7. Support an alternative allocation system that requires each OPO to have at least three back-up transplant programs ready to accept the kidney if the first program declines. This will reduce the time the kidney is out of the body and in cold storage and decrease the risk of wastage.
8. Fund/encourage a collaboration with CMS to support an ongoing learning action network to bring experts together to continue to discuss the discard problem, complete plan-do-study-act projects designed to increase utilization, and share best practices among OPOs and transplant programs to reduce the kidney discard rate.

***Teresa Shafer, RN, MSN, CPTC***, Donation and Transplantation Consultant and Expert Reviewer, Royal College of Surgeons of England, Clinical Effectiveness Unit, Center for Evidence in Transplantation. Ms. Shafer is a founder and former co-chair of the National Organ Donation Breakthrough Collaborative (ODBC) and for 30 years has been chief operating officer of one of the nation's largest OPOs.

OPTN clings to a zero-sum gain as the basis for organ allocation modeling with the resultant requirement for transfer of organs. For organ allocation, the sole issue that should be addressed is increasing organ recovery performance by donor service area (DSA)/State/community. Instead, poorly performing DSAs have focused on erasure of boundaries that will allow them to take from other DSAs instead of increasing donation in their own DSAs, which would help not only their own patients but patients throughout neighboring communities.

For example, if New York came up to the national average where half of the nation's OPOs already function, the State would have 181 more livers for transplant per year vs. 130 more livers in the SRTR model of the Acuity 250.500 system, by taking from other communities through broader sharing. Similarly, the Massachusetts/New England DSA would have 79 more livers for transplant vs. the SRTR modeling system where Boston would have 61 more livers; California would have 18 more livers for transplant per year vs. in the SRTR modeling system where they would have 14 more livers; Minnesota would have 38 more livers for transplant vs. in the SRTR modeling system where they would have 41 more livers.

With performance improvement of a modest degree to the national average—where half the nation's OPOs already perform—in the four States/DSAs above, 265 more livers would be obtained for patients from their own DSA/State. On the other hand, removing organs from other

DSAs/regions with the acuity circles would bring in 254 organs to those States. Improved performance in these communities would outdistance any gains that it will receive by the disruptive policy OPTN passed in December. The solution of improving performance in these organizations/DSAs is not only a moral no-brainer, but also common sense.

Finally, dramatic increases in donation can be achieved. Numerous communities have drastically increased donations after a change in focus/structure/reinvestment in donation has occurred at the DSA level. For example, the Organ Donation Breakthrough Collaborative produced a nationwide increase in donation by 24.5 percent across the country in 36 months.

**Carol LaFleur**, founder of the Northeast Kidney Foundation (1972), a patient advocacy organization. The burden on our healthcare system by chronic kidney disease, especially dialysis, is overwhelming. Meanwhile, 80 percent of the national transplant waiting list is comprised of those waiting for a kidney, and they may have to wait 7 to 10 years.

The Organ Donation Recovery and Improvement Act provides for reimbursement of travel and subsistence expenses, but not lost wages or child care and other expenses. Donors on average incur \$4,200 in expenses, which prevents some prospective donors from donating. Eliminating this barrier would help increase transplantation by as much as 25 percent, which would in turn save healthcare dollars and lives.

**Rachel Bennett Steury** expressed disappointment in the lack of time available for public comments at the ACOT meeting on May 20. With just five people given time to share their input on such an important matter as living donation, it seemed that the public's input was of little importance to the conversation. She hoped that future meetings would allow for more dialogue and that public comments would be considered seriously in the decisions being made about donation.

**Harvey Mysel** is a two-time kidney transplant recipient. He started the Living Kidney Donors Network to help those in need of a kidney find a living donor, which has been extremely rewarding. However, he has also spoken to kidney donors who have critical financial challenges post-transplant because they cannot return to work as planned and, therefore, they cannot meet their financial responsibilities. This situation deters others from donating.

**G. Kenneth Harrison, M.D.**, Medical Director for Patient Safety and Quality, Willis Knighton Health System, Shreveport, LA. Dr. Harrison is concerned about the proposed reallocation of organs being considered. This would be extremely detrimental to the health and well-being of his patient population in Louisiana. If this proposal were to be enacted, they would lose many of their donated livers to the Dallas–Ft. Worth metroplex region. The regional transplant center in Shreveport serves a largely rural population that is socioeconomically depressed and lacks resources to travel outside this area. Likewise, the population has a high incidence of serious illnesses, including hepatitis C, non-alcoholic steatohepatitis, and alcohol abuse with related conditions. If they were to lose more organs to other more densely populated areas, their patients would undoubtedly suffer and many more would certainly die. Dr. Harrison strongly urges ACOT to reconsider and to keep these circumstances in mind.

**Billy Wynne**, Executive Director, National Coalition for Transplant Equity (NCTE). NCTE is an alliance of patient advocates, OPOs, transplant centers, and other stakeholders. NCTE supports OPTN's December 2018 adoption of the Acuity Model for organ distribution. The broader

sharing enabled by this policy will reduce the average sickness of patients at the time of transplant, reduce costs to the system, and save lives.

In reaching their decision, OPTN reviewed a comprehensive body of evidence from various sources and voted overwhelmingly to adopt the Acuity Model. Nevertheless, members of Congress are calling for a reversal of OPTN's decision. The newly adopted policy will save lives, reduce the average sickness of patients at the time of transplant, and reduce costs to the transplant system.

As implementation of the new policy proceeds, NCTE encourages ACOT to uphold OPTN's evidence-based decision and support continued implementation without delay.

**Mark Russo, M.D.**, Medical Director, Liver Transplantation, Carolinas Medical Center, Charlotte, NC. Dr. Russo does not support the 500-mile redistribution system for liver transplantation because it will harm rural patients in North Carolina waiting for a liver transplant. In 2016, the liver transplant community agreed to implement a new redistribution system; it has worked for several years and this is the one we should implement.

**Glenna Frey**, co-founder and co-executive director of Kidney Donor Conversations, Whitehouse, OH, has been a nephrology nurse for over 30 years. Her husband has polycystic kidney disease (PKD) and received a kidney transplant from her niece 16 years ago when she was only 20. Their daughter also has PKD, and Ms. Frey donated her kidney (nondirected) in 2017. In 2018, they started Kidney Donor Conversations to increase awareness of living kidney donation. She spent around \$1,000 to donate her kidney to a stranger and fortunately did not have lost wages during the 3 months needed for recovery. However, not all potential donors have this benefit, nor the means to spend any money toward donation, therefore they do not donate. Ms. Frey supports immediate expansion of NLDAC to raise the income cap and reimburse lost wages and other expenses so all costs to donors are covered.

**Charles Van Buren, M.D.**, Emeritus Professor of Surgery, University of Texas Medical School Houston. The deficiencies in the UNOS liver allocation policy recently implemented are four-fold:

1. The policy fails to address the variances in listing criteria between regions. If organs are a national resource, then an acceptable candidate for this national resource should be identified based on universally agreed upon criteria, not local or regional whims. The tremendous number of variances to upgrade model for end-stage liver disease (MELD) values in New York recipients are an example of how regional variances can exacerbate imbalances between supply and demand.
2. The tolerance of unacceptable utilization rates of donation-after-circulatory-death (DCD) livers in some regions exacerbates the inadequate supply of transplantable organs. The surgeons in New England and San Francisco fall far below their peers in use of DCD livers. While squandering this local resource they clamor for others to offer the best resources available to them while they discard usable livers. The UNOS policy rewards worst behavior rather than encouraging adoption of best practices.
3. The stated policy is illegal. Many of the centers that will benefit from the new UNOS liver policy are in States that have expanded Medicaid. Many programs that will lose livers are located in States that have chosen not to expand Medicaid. If it was illegal to withhold Federal funds from States to coerce them into expanding Medicaid (Supreme

Court decision, 2012), why is this coercion permissible to force exportation of livers as the means of punishing State policy? It is certainly an arguable point.

4. The process for implementing this liver allocation policy was remarkable for its lack of due process, as well as its break with the precedent for establishing allocation policy. A policy for liver allocation had been recommended by the UNOS Liver and Intestine Transplantation Committee and recommended by the board for implementation in 2017. Instead, UNOS initiated a new process under the auspices of the ad hoc geography committee with no opportunity for all regions to be represented. When this committee drafted three proposed policies, public comment on the proposals via the UNOS website could only be registered by first choosing one of these three flawed proposals. This process is more reminiscent of process in the former Soviet Union rather than agency contracting with the U.S. Federal Government. UNOS admits that very little of this commentary was considered before implementing the policy. Finally, the desire for UNOS to forge ahead in implementing this policy ignoring a Federal court order not to do so is unprecedented in transplantation policy and, to Dr. Van Buren's knowledge, in the executive office implementing health care policy. It is symptomatic of the rogue organization that UNOS has become. UNOS should forfeit its role as the arbiter of transplant policy, since it has proven itself incapable of being a fair-minded steward of the gifts donor families have entrusted to their care.

**Al Roth**, Stanford University, is a member of NLDAC's Advisory Board and shared the 2012 Nobel Prize in Economics in part for his work on kidney exchange. He expressed support for increasing NLDAC's budget, allowing it to serve more donors (by raising the income cap, and allowing it to pay a wider variety of donor expenses (including child care and lost wages). These changes would increase NLDAC's effectiveness and could be acted upon immediately.

**Vincent P. Casingal, M.D.**, a transplant surgeon involved in liver, kidney, and pancreas transplantation, expressed concern regarding allocation of liver transplants. He is a volunteer on the UNOS Kidney Committee and is currently working to help gain consensus regarding future kidney allocation. He believes that change is needed in kidney allocation.

Dr. Casingal does not agree with the current plans to change liver allocation. The system currently in place does not consistently take into consideration well thought out tenets of the final rule. The changes will significantly disrupt liver transplantation and the efficiencies currently gained without adding significant benefit. He is committed to helping find the best answer, which may include different and innovative changes or further discussions regarding goals and limitations of allocations.

In summary, while Dr. Casingal supports changing the liver allocation system to allow broader sharing, he does not support the Acuity Circle model as proposed. He therefore asks that this be put on hold and that UNOS reconsider a different model for sharing.

**Michael Lollo**, a current organ donor whose company covered his wages. An average of 13 people die every day waiting for a life-saving kidney transplant. Yet people are prevented from donating organs simply because they would have to lose their wages to do it. The cost saved to the government by taking these people off dialysis is huge. Therefore, he recommends immediately expanding NLDAC.

**Bobby McLaughlin** supports expansion of NLDAC to raise the income cap and reimburse lost wages and other expenses tied to living kidney donation. As an active advocate for and educator

about kidney donation, he sees that many people would donate if they were not penalized by the expenses they would incur.

**George Loss, Jr., M.D.**, a transplant surgeon specializing in the use of marginal, underutilized liver allografts, leads the largest liver transplant program in the United States. More than half of the livers they use come from outside his State. In addition, he served two terms on the UNOS Liver/Intestine Committee and on several liver/intestine work groups.

In late 2017, the Liver/Intestine Committee and eventually the UNOS Board of Directors passed a compromise liver distribution proposal. This proposal, like all compromise proposals, was far from perfect. It was years in the making, required all parties to make concessions, and was based on the guiding principles listed below:

- The current system of MELD, OPOs, and regions by and large works very well.
- One goal is to decrease variance in median MELD at transplant.
- Local priority points should be given to prevent unnecessary flying for clinically insignificant MELD score differences.
- We should strive to minimize the inevitable increase in the overall flying percentage (surrogate for cost).
- Priority should be given to laboratory MELD (sickest first, those at highest risk of death) rather than allocation MELD.
- Cold-ischemia time should be minimized for the most at-risk livers.
- We should incentivize DSAs (OPOs + their transplant centers) to pursue and use the highest-risk livers locally and encourage improved DSA performance.
- The new policy should be agile and adaptable. Measures of success should include not only variance in MELD at transplant, but other metrics including death on the list (rates and counts), post-transplant death (rates and counts), discards (rates and counts), flying percentages, effects on minority and low-income populations, and increase/decrease in counts of total transplants performed.

Before that new liver policy was implemented, however, it was challenged in court. The Liver/Intestine Committee met by urgent conference call. We believed our policy was nuanced and in compliance with the Final Rule, and we voted overwhelmingly to urge UNOS/HRSA to fight the suit. UNOS/HRSA declined and instead we were asked to change the policy and eliminate both DSA and region as units of liver distribution. Under tremendous time constraints, we created a revised policy very similar to the one passed the prior year, but without DSA and region as distribution units. The Liver/Intestine Committee voted to send two versions of this new proposal (called B2C) out for public comment. But, UNOS and/or HRSA overruled again and chose to send out one version of B2C and a second proposal, Concentric Circles, a model introduced by a University of California–San Francisco faculty member and one that had never undergone modeling analysis. The committee then met in person and voted (narrowly) to recommend the B2C liver policy to the UNOS Board of Directors. At the UNOS board meeting, the Board of Directors chose to ignore the recommendation of the Liver/Intestine Committee and instead voted to adopt the Concentric Circles model.

Many of us on the Committee volunteered countless hours over many years to carefully consider a very complicated problem. As transplant professionals, transplant recipients, members of donor families, and interested citizens, we view ourselves as stewards of a scarce and sacred resource—the donated organ. We take this responsibility very seriously. Our years of work was thrown out,

policy was created at gunpoint, public comment and data analysis were rushed, and, after all of that, the UNOS Board of Directors ignored our recommendation. It seems this process was hijacked long ago. This is not good governance. This is not good policy. This is certainly not democratic. This does not incentivize our underperforming colleagues to improve. And sadly, this is not good for our patients.

### **Recommendations**

Recommendation 1. *Eligibility guidelines for travel costs for living donors to 500 percent of the FPG for U.S. households.*

All agreed.

Recommendation 2. *Amend guidelines to waive income verification for donors with less than \$500 of anticipated travel and subsistence.*

All agreed.

Recommendation 3. *Alter the current program guidelines to support travel and subsistence costs in the United States for living donors, whether nondirected or directed.*

All agreed.

Recommendation 4. *Encourage a permanent mechanism for lost wage reimbursement for non-directed living donors in conjunction with the travel and subsistence costs.*

All agreed to endorse the concept (but ACOT must follow up on it).

Recommendation 5. *Alter current guidelines to improve reimbursement so that it includes reimbursement for living donors' child care and elder care expenses in addition to travel and subsistence costs.*

All agreed to endorse the concept.

Recommendation 6. *Require HRSA programs that support living donors and transplant patients to inform patients about NLDAC.*

All agreed.

Recommendation 7. *Create a coordinated innovation and transplantation work group that links all U.S. agencies that work on transplantation.*

All agreed.

Recommendation 8. *CMS should add the word "declare and/or excise" in the direct cost recording.*

Dr. Mulligan will send this to everyone to be sure of the correct wording, so they can vote by email.

### **Adjournment**

Dr. Mulligan thanked everyone and Mr. Holloman adjourned the meeting at 5:05 p.m.