

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

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

Virtual Meeting, April 7, 2020

Present Members

Voting Members

Linda Cheatham; Jay Fishman, M.D.; Andrew Lee, M.D., FACS; Janice Whaley, MPH, CPTC, CTBS;

Non-voting (Ex Officio) Members

Jonah Odum, M.B.A., M.D., Ph.D. [for Nancy Bridges, M.D.]; Diane Corning, Esq.; Sridhar Basavaraju, M.D.; Scott Brubaker

Executive Secretary

Robert Walsh

General Counsel Staff

Laura Odwazny; Emily Marcus Levine, J.D.

Welcome and Opening Remarks

Robert Walsh, Executive Secretary, ACOT

Mr. Walsh opened the meeting at 10:16 a.m., thanked everyone for their patience while dealing with technical difficulties, and conducted a roll call of the ACOT Members and Ex-Officio Members.

HRSA Division of Transplantation (DoT) Organ Transplantation Program Update

Frank Holloman, Director, HRSA, DoT

Mr. Holloman began by providing a quick overview of the role the DoT has within the organ donation and transplantation community. The Division is within HRSA's Healthcare Systems Bureau and is the primary federal entity responsible for oversight of solid organ transplantation and for initiatives to increase organ donation in the United States.

DoT oversees the Organ Procurement and Transplantation Network (OPTN) for compliance with the statutory framework, including the National Organ Transplant Act (NOTA), the regulatory framework, including the OPTN "Final Rule", and OPTN contract requirements.

NOTA and subsequent amendments authorized the establishment of the OPTN, the Scientific Registry of Transplant Recipients (SRTR), the Living Donor Reimbursement Program, and the Organ Donation Public Awareness Program. This amendment also provided Grant Authority to fund demonstration projects and public and professional education. The regulatory framework of OPTN is guided by the Final Rule, which provides high-level requirements for the operations and functions of the OPTN and regulatory requirements for OPTN membership and composition,

OPTN policymaking related to organ allocation, compliance reviews, patient safety, data collection, organ procurement, and the establishment of ACOT. Currently, the OPTN contractor is the United Network for Organ Sharing (UNOS).

DoT has oversight of the Scientific Registry of Transplant Recipients (SRTR) whose role is to support ongoing performance evaluation of solid organ transplantation within the United States and provide analytic support to the OPTN to aid in the formation and evaluation of policies, allocation models, and reporting outcome rates. The SRTR contract is currently with the Minneapolis Medical Research Foundation Chronic Disease Research Group (MMRF).

DoT is also responsible for the Organ Donation Outreach and Organ Donation Awareness Program to close the gap between the supply and demand of transplantable organs. Additionally, DoT oversees the National Living Donor Assistance Center (NLDAC) which targets financial barriers to living donors and provides reimbursement for transplant-related expenses. HRSA staff members also serve as ex-officio, non-voting members on the OPTN Board of Directors, OPTN Executive Committee, and all OPTN Committees.

Mr. Holloman then presented a flow chart demonstrating the relationships between the U.S. Department of Health and Human Services (HHS), HRSA, OPTN, OPTN Contractor, and SRTR Contractor. Aside from these working relationships, the division receives assistance and oversight from four other sister agencies within HHS: the Centers for Medicare & Medicaid Services (CMS) and oversight on issues relating to transplant centers and Organ Procurement Organizations (OPOs); the Centers for Disease Control and Prevention (CDC) on issues relating to transplant-related communicable disease transmission; the Food and Drug Administration (FDA) relating to the regulation of transplant productions; and transplant-related research provided by the National Institutes of Health (NIH).

In 2019, the total number of transplants reached an all-time high of 39,718 transplants and 11,870 deceased donations. As of March 19, 2020, there were 112,382 transplant candidates on the waiting list. The Organ Donation Awareness Program uses successfully identified interventions to shrink the number of transplant candidates. These interventions focus on increasing registration for deceased donation, promoting family discussion about organ donation, and increasing awareness on the risks and benefits associated with living organ donation.

OPTN Update, COVID Monitoring

Brian Shepard, OPTN Executive Director

2019 was a record-setting year for organ transplants. There were 7,400 living donor transplants completed, an 8.7% increase in the number of transplants done and a 10.7% decrease in the number of donors since 2018. However, due to the COVID-19 (Coronavirus) pandemic, there has been a considerable decrease in the number of transplants within the first three months of 2020. Currently, the number of deceased donor transplants has dropped by approximately 30%. Based on the models showing the spread of Coronavirus peaking during April or May, the rate may continue to drop. Additionally, there has been an increase in the number of patients being made inactive on the waiting list and living donor transplants have almost stopped completely.

Graphs illustrating the decrease in donor transplants by week, geography, and organ type, depict that all parts of the country have been affected, although not at the same time and the same amount. The impact in some geographic regions is still unknown as the spread and impact of COVID-19 has not been felt fully and those areas will continue to be monitored. Although the

pandemic is global, it is important to support the circumstances occurring within that region as each region and environment has unique circumstances.

OPTN has taken several steps to monitor the COVID-19 situation federal agencies' guidance to OPOs and hospitals on how to handle the pandemic. UNet has been updated to include a reporting tool so that the challenges and observations within the current climate can be recorded. Furthermore, OPTN provides a daily report to HRSA on the current volumes and activities across the network that can be shared with their partners throughout the government.

OPTN has made emergency changes to some data requirements, including the addition of codes for COVID-19 to UNet to better understand the scope and the scale of impact on donation and transplantation activities and learn of what other activities may be potentially impacted. Additionally, specific data requirements relating to the registration of candidates and follow-up for transplant recipients have been waived, and enforcement of these requirements has been relaxed as to not place patients in high-risk situations. Wait time continuation has been incorporated for candidates that have been inactivated due to the pandemic. Lastly, adjustments will be made to the Membership Professional Standards Committee (MPSC) peer reviews to reasonably handle difficult judgment calls that will need to be made in the coming months.

All OPTN committee meetings through May have been converted to virtual meetings. This applies to the previous three regional meetings as well. Site surveys moving forward will be done virtually and can be rescheduled due to Coronavirus related activities. However, the in-person OPTN Board Meeting is still scheduled for June in Richmond, Virginia, but will be held virtually if necessary.

Discussion

Dr. Fishman explained that there could be a positive takeaway from the present circumstances. As most people are working remotely, meeting with patients remotely, and collecting data in new ways, it has shown the redundancy of patients going into the clinics as often. COVID-19 has highlighted the need for better coordination of data across the entire U.S. to facilitate access to people on the front lines. The published data or peer-reviewed data relating to the effects of the Coronavirus should be shared with professionals not affiliated with academic centers. Mr. Shepard replied that data-sharing relates to IT work with OPOs and transplant hospitals employing their own IT companies as opposed to smaller centers or departments. Currently, about 60% of the data elements within the system are being sent automatically from OPOs and large centers. The ultimate goal is to allow more partners to directly import data, images, lab results, and other relevant data into the system. Lastly, he agrees that sharing and publicizing data relating to the pandemic is the best way to support the community in the present environment.

Dr. Odum followed up on the comments made by Dr. Fishman, that he understands that there are numerous enterprises developing registries of COVID-positive patients within the transplant community, such as the University of Washington. He posed the question of having a central organization compile the various data registries and provide up-to-date overviews of the current rates and data on a weekly basis. Mr. Shepard responded there is not a vast amount of data within the system relating to COVID-19. He believes the amount of information within the database concerning Coronavirus will be limited as the transplant community is intentionally avoiding patient exposure.

Dr. Lee asked about the availability and current situation concerning COVID-19 testing for potential organ donors. Mr. Shepard stated that it is varied. However, almost all donors are tested for Coronavirus with centers now asking what type of test was done, instead of asking if a test was done.

Dr. Lee followed up by asking if OPOs have a standardized policy for COVID-positive donors. Ms. Whaley stated that the American Society of Transplantation's (AST) recommendation is to test all donors. The challenges lay with the need to send samples elsewhere for testing and the delay it causes. Dr. Fishman interjected with the notion of OPTN preparing a list of what tests are being done. This is absolutely essential for patient management and staff safety. Mr. Shepard pointed out that OPOs have been working tirelessly to provide testing to all donors and provide test information to transplant hospitals. No one is knowingly transplanting COVID-positive donors.

Mr. Walsh highlighted that while the committee was discussing updates concerning COVID-19, the discussion was not limited to things the OPTN could do, and welcomed input on a broader scale regarding the pandemic.

Dr. Merion wanted to build on the comments made by Dr. Odim. He asked if the OPTN or any other committees have broached the topic of asymptomatic medical staff or persons inadvertently transmitting the Coronavirus to transplant donors or recipients. Furthermore, when looking at transplant patients who contracted a similar virus, SARS, they became viral super shedders with higher risks to the people around them. Mr. Shepard answered that Disease Transmission Advisory Committee (DTAC) has discussed this and is working with AST and the American Society of Transplant Surgeons (ASTS) to gather information. The notion of potential policy and data change interventions has been outlined in a three-tiered approach: tier one data affects behavior immediately, tier two data affects future understanding, and tier three adjusts how things are conducted during the epidemic.

Mr. Walsh directed a question to Ms. Whaley regarding whether OPOs have expanded use of donor recovery centers outside of the hospitals for procurement to reduce bed space utilization? Ms. Whaley answered that OPOs are using recovery centers, but that the OPOs have committed to testing donors for COVID-19 prior to transferring.

OPTN Update, including Organ Allocation Policy Changes

Brian Shepard, OPTN Executive Director

The Final Rule allows the use of geography, proximity, organ transport cost analytics, and cold time impacts on the organ, but in a consistent manner that supports the other goals of the Final Rule. To improve on this, DSA-based allocation is evolving into a circle-based system for all organs. So far, four organs have implemented policy changes: lungs, heart, liver, and VCA. In December 2020, circle-based policy changes will take effect for the kidney and pancreas. The most recently implemented policy has been for liver transplantation, which took effect on February 4, 2020. Data on the impacts of the policy change has been collected since implementation. Recently, this data has been impacted by the Coronavirus pandemic, and the data collected during the period impacted by the pandemic may be a misrepresentation of the policy's effects compared to its effects during a normal environment. It will be at least six months until accurate data is developed and collected.

The outcome of implementing these policy changes is to establish a coherent, consistent boundary that can be applied nationally. For example, DSA-based policy established near boundaries exclude a candidate or donor hospital that is on the other side of a river or state line. The Continuous Distribution model was developed to establish circle-based boundaries and candidate point scores. A candidate's point score is the total score calculated from the score given within a predetermined set of categories and then ranked among all candidates within that set. Adjustments can be made to the weight of each criterion within the candidate's score.

The Thoracic Committee was the first to work through this model. Having already identified and categorized the attributes, they are currently developing the prioritization of these attributes, their weight against each other, and their point conversion. The next steps to develop the policy proposal will be the building of framework, SRTR modeling, opened up for public comment and community discussion and then going to the board. This method of Continuous Distribution and adoption of circle-based policies will be applied to all organs.

Mr. Shepard also introduced the Application Programming Interfaces (APIs) that have been created for over half the data within UNet, in conjunction with the electronic health record builders, to enable the exchange of data between program interfaces. The offer filter tool has been built into the program, enabling the mix-match of set donor criteria and calculated personalized criteria based on the individual center's past behavior. The personalized criteria provide detailed information on organs they have previously accepted and include the option to exclude those organs.

Mr. Shepard provided an update on the early results of the OPTN Kidney Accelerated Placement Project, which is meant to improve placement and utilization of kidneys at highest risk of discard. Early results are promising indicating a 14% increase in placement of national kidney allocations coordinated by the Organ Center. These kidneys are at highest risk of discard after not being placed regionally. Finally, Mr. Shepard provided an update on the Systems Performance Committee (SPC), a special committee of the OPTN, which identified aspects of OPTN operations beyond allocation policy that can lead to more efficient matching and transparency. Based on the SPC's recommendations the OPTN is developing dashboards and data tools, additional organ offer filters, upgrades to DonorNet mobile, and methods to share radiology imaging.

Discussion

Ms. Whaley asked if there is any data that shows an increase or decrease in lung utilization, or if there have been significant lung discards since the new lung allocation policy began in November 2017. Mr. Shepard could not recall the exact data offered to forward the data report to the committee.

Ms. Cheatham expressed a concern raised during recent discussions in the community on allocation policies implying that big centers were not procuring organs. She asked if the OPTN is looking at the imbalance? Mr. Shepard clarified OPOs handle procurement and that the OPTN has performance metrics for OPOs. He also reiterated the policy goal of recent changes to allocation policies is to remove artificial boundaries preventing transplantation to the most urgent patient.

Dr. Odum asked: Are any centers using the APOL1 genetic marker to discriminate against African Americans in situations where they are one of the ten variables and a high kidney donor

profile index (KDPI) score to learn if a deceased donor has high-risk variance when making their decision to accept an organ? Mr. Shepard replied with no knowledge of this happening. However, the chief medical officer, Dr. Klassen is involved with APOL1 studies and will get the answer to that question.

Ms. Corning referenced kidney and pancreas having full implementation by December 2020 and wondered if that meant staggered implementation. Furthermore, she asked if implementation would be affected by COVID-19. Mr. Shepard did not mean to imply staggered implementation, but that there are more details upcoming and all will be programmed at the same time in December. At this time, it is unlikely that the Coronavirus will impact the timeline.

National Living Donor Assistance Center (NLDAC) Reimbursement of Lost Wages Pilot

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

The NLDAC Travel and Subsistence Program was established in 2006 and has been operational for 13 years, with current funding through August 2024. The program's mission is to reduce the financial disincentives to living organ donation through reimbursement of travel and subsistence expenses incurred in relation to living organ donation. NLDAC's advisory group is tasked with providing input on policy development, reporting on major outcomes and project performance, and provide expertise on a wide range of disciplines throughout the transplantation and dialysis community.

Dr. Merion reported that since the initiation of the NLDAC in 2007 the program has received 10,240 applications for assistance resulting in 5505 transplants and \$19,164,758 in reimbursed donor expenses. There are 213 transplant centers in the U.S. that have filed at least one application for travel support, with 92% of applicants for kidney donors. Since the program's inception, over 75% of donors report that they would not have been able to donate without the program. Over the last 10 years, there has been a steady increase in the number of applicants, with a record number of applicants over the last two years resulting from increasing awareness campaigns. The program demographics match well to national characteristics for age and sex, however, the percentage of African American and Hispanic donors is considerably higher than the national average. Financially speaking, about 55% to 60% of support is spent on transportation and lodging, with one out of every six dollars spent on food.

Studies conducted regarding life satisfaction and depressive symptoms of roughly 3,000 participants yielded results of a statistically higher satisfaction of life among donors than non-donors. Additionally, a scale was used to analyze potential depressive symptoms of donors and those who were disqualified as donors. The results demonstrate a slight statistically higher rating in donors than non-donors. However, the study concluded that both donors and disqualified donors had higher satisfaction with life and lower levels of depressive symptoms. However, this is believed to be a typical post-surgical phenomenon that is short-lived. At this time, no correlation can be made on a long-term scale.

Dr. Merion stressed the importance of program awareness to potential recipients to facilitate conversations with potential donors about the program. To increase program awareness, the NLDAC established a new resource in December 2019 that includes real-time data detailing individual center's activity over time. The NLDAC intends to add further enhancements to this reporting in the coming years.

In response to the COVID-19 pandemic, there has been a significant drop in monthly activity and two-thirds of programs have reported saying they have suspended living donor evaluations. The suspension of living donor evaluations could lead to an extended period before living donation returns to previous levels as there is a usually long slope from evaluation to donation. Some centers are continuing operations but are requiring donors to be local and quarantined for fourteen days before moving forward with donation surgery. As this period of time exceeds the travel period allowed under the program's current policy, NLDAC has requested and received permission from HRSA to have a COVID-19 exception which extends the travel period for donors under the current circumstances.

Recently, the NLDAC advisory group's scope was expanded to encompass the development and initiation of the Lost Wage Reimbursement Program, a companion project administered by the NLDAC. This is a pilot project that allows up to \$5,000 in lost wage reimbursement and an \$8,000 combined maximum with the Travel and Subsistence Program.

The mission of this pilot is to test the impact of lost wage reimbursement on the decisions of individuals to initiate an evaluation and aims to inform HRSA on the most effective and efficient mechanism to support it. The proposal targeted geographic and sociodemographic diversity with five designated champion transplant centers to help with the structural formation of the program.

The states that are currently participating or have planned programs are, with states with a champion center indicated by an asterisk:

- Alabama*
- Arizona
- California*
- Florida
- Illinois
- Maryland*
- Minnesota
- New York
- Ohio*
- Pennsylvania
- Tennessee
- Texas
- Washington
- Wisconsin*

The program expects the impact of the reimbursement of lost wages under the pilot will largely impact potential donors who would have been previously unidentified. The program expects the pilot will shine light on demographic characteristics that may correlate with barriers to living donation. The NLDAC has created brochures in English and Spanish and two videos for use at transplant centers to help educate potential living donors and transplant candidates on living organ donation and the reimbursement available through the NLDAC.

Based in part on recommendations made at the May 19, 2019 ACOT meeting, HHS has taken actions to implement Advancing American Kidney Health Initiative to expand the expenses eligible for reimbursement through the Program. In response NLDAC is developing a system redesign to reduce the burden on the transplant center staff for submitting applications and required documentation related to the expected expansion and to retain efficiency within operations.

Discussion

Mr. Walsh relayed a question posed by a participant in the chat function of the webinar regarding the availability of NLDAC data about which centers are using or submitting applications. Dr. Merion answered that there are separate awareness and marketing activities, but the data has not

been made publicly available. At this point, every program within the country has a filer and there should be a mechanism employed to make potential donors aware of the Transplant Assistance Center.

Ms. Whaley asked if there was a reason for disparities in living donations with Hispanics and African Americans. Dr. Merion responded that NLDAC does not have definitive answers; however, by definition, all NLDAC applicants come from very modest means.

Ms. Cheatham asked if the NLDAC website been optimized to appear in search engines when people are looking for information about being a living donor and financial reimbursement? Dr. Merion answered that it has been and there is an ongoing focus on search engine optimization.

Expanding HOPE: Possibilities for new HIV-to-HIV Transplants in the United States

Dorry Segev, M.D., Ph.D., Professor of Surgery and Epidemiology, Associate Vice Chair, Department of Surgery, Johns Hopkins Hospital

The HIV Organ Policy Equity (HOPE) Act, which was signed into law in November 2013 removed a prior prohibition on the procurement of organs from HIV positive donors and allowed for research into transplanting organs from HIV-positive donors into HIV-positive recipients consistent with research criteria developed by the NIH. The Act requires that such transplants only be performed under these research protocols unless HHS in consultation with the OPTN determines that the practice is safe and further research is unnecessary.

Dr. Segev presented findings to date from this research highlighting the experience at 33 kidney and 20 liver transplant programs across the U.S. Since the first transplant under these research protocols in March 2016 there have been 154 transplants into HIV positive recipients from 87 HIV positive donors with 100% patient survival.

Dr. Segev suggested that several logistical barriers exist to the possible expansion of the number of transplants under these protocols. Some of the barriers relate to OPTN systems that could be modified to more easily facilitate matching of HIV positive donors and recipients. Dr. Segev argued that while the research protocols developed by NIH are still warranted experience since the protocols were published in 2015 requires reevaluation. Specifically, he argued that the experience requirements under the research criteria may be unnecessarily limiting research of transplant of organs other than kidneys and livers.

Discussion

Dr. Fishman agreed that the availability of expertise in HIV and infectious disease should allow for HIV-positive transplants to proceed. Additionally, he stated that the HIV status of the donor or recipient does not change the technical aspects of the transplant, which he suggested eliminates the need for experience in HIV-positive transplants of a specific organ.

Dr. Odum stated that the experience requirement of five negative-to-positive heart or lung transplants should not be a significant barrier. He added that transplants performed under the HOPE Act remain under a research protocol and are not yet the standard of care. The intermediate and long-term effects are still unknown, and the biopsy requirement is within the

context of that research protocol. Dr. Segev responded that in 2015 all these requirements seemed reasonable, but presently there is a much larger pool of data. Also, the elimination of the biopsy requirement is based on the rate of invasive biopsies done on other patients, which is .05%.

Ms. Whaley asked why this is still a research study after five years. Dr. Segev said there are no hard numbers or criteria for when it will be sent to the clinical realm, other than the stipulation in the HOPE Act that requires the HHS Secretary to review the results yearly and make a decision. A recommendation could be made to release all research requirements and allow for clinical practice while still conducting research. A comparison was made with the analog of Hepatitis C without any research requirements or protocols to those of HIV-to-HIV.

Dr. Fishman followed up with the Coronavirus as an example, as he does not think Hepatitis C is a viable comparison. For instance, superinfections and strain variation have not been issues, but that may only be due to the restrictions in place. Perhaps it should be kept in the research realm while being re-examined in terms of the inclusion criteria and building out experience so that more centers can perform those types of transplants.

Empowering Patients, Partners, and Providers to Increase Kidney Transplantation

Renee Dupee, JD, Director, Division of Strategic Innovation, Evaluation, and Communication, CMS, CCSQ, iQuality Improvement, and Innovation Group

Christopher McLaughlin, Chief of the Organ Transplantation Branch, HRSA, DoT

Ms. Dupee and Mr. McLaughlin reported on recent efforts in response to the President's Advancing American Kidney Health Initiative. CMS has proposed the ESRD Treatment Choices Payment Model Test with a goal of improving options for patients with end stage renal disease (ESRD). A component of this larger activity is the CMS-HRSA Transplant Learning Collaborative, which aims to achieve 11,000 additional kidney transplants over next 4 years. Ms. Dupee and Mr. McLaughlin presented the proposed activities and goals of the learning collaborative, which intends to decrease the national discard rate of procured kidneys from 19% to 15% and increase annual growth in the number of deceased donor kidneys transplanted from 5% percent to 15%.

They highlighted how the learning collaborative intends to build on the work already performed by the HRSA supported OPTN Collaborative Innovation and Improvement Network (COIIN) pilot project, which tested collaborative learning with over 50 kidney transplant centers to increase effective and safe utilization of moderate to higher risk kidneys, reduce risk-avoidance behavior, and encourage changes in waitlist management, organ acceptance, and post-transplant care.

Discussion

Ms. Cheatham asked about the timelines and whether participation would have consequences for OPOs and transplant centers. Ms. Dupee answered that the effort is planned to begin in 2020 through 2024 and that the intention to engage the entire community but there is not any intention for penalization for not participating.

Ms. Whaley asked if there will be any part of the change packet from previous collaboratives that still hold true for this one. Ms. Dupee stated that previous packets were not used as a

foundation, but it is possible some content has remained or evolved. Mr. McLaughlin emphasized the new effort will include a component focused on utilization of organs.

Recommendations

Recommendation 66

ACOT recommends that the Secretary direct NIH and CDC to re-examine impediments to expanding transplants performed pursuant to the HIV Organ Policy Equity (HOPE) Act. Specifically, ACOT recommends that this reexamination include the following considerations:

- a. How HOPE donors could be better managed in the organ allocation process
- b. Mechanisms through which teams willing to recover HOPE organs can be more expeditiously identified
- c. Best practices for experience in HIV+ transplants.

ACOT suggests that this consideration might be appropriately managed by allowing centers with relevant experience in HIV- transplants in each specific organ, in combination with appropriate Transplant Infectious Disease and HIV care experience, to participate in these studies/procedures.

- d. Best practices for biopsies in living donors

ACOT further notes that the requirement for pre-donation biopsy in living HOPE donors seems potentially unnecessary – this is worth considering in the context of research vs. standard of care practice. The data for the requirement for living donor biopsies merits reexamination. Less than 0.05% of living donors in the United States currently undergo pre-donation biopsy. A back-table research biopsy can be performed without harm to the donor.

ACOT further recommends that the Secretary direct HRSA to address impediments to expanding transplants performed pursuant to the HIV Organ Policy Equity (HOPE) Act. Specifically, ACOT recommends that HRSA work with the OPTN to:

- e. Unmask national centers in test match runs, which may have caused the loss of many HIV+ organ donors
- f. Consider a statement to OPOs that HIV status alone is not a valid donor rule out
- g. Require OPOs to identify and work with teams willing to recover HIV+ donors
- h. Add the evaluation of HIV+ referrals to the OPO process audit.

Recommendation 66 was approved unanimously.

Recommendation 67

ACOT recommends that the Secretary consider HHS actions and provision of recommendations to improve testing, including the communication and reporting of test results and other data to the OPTN, with respect to the microbiological evaluation of organ donors and transplants.

One aspect for consideration is an improved centralized mechanism for reporting/viewing donor culture and serology results that become available post-transplant.

Another aspect that the ACOT urges the Secretary to consider is improved validation of laboratories performing serologic and other assays and the role of histocompatibility laboratories.

Recommendation 67 was approved unanimously.

New Business

Ms. Cheatham expressed concern that the ACOT is underutilized and encouraged more regular meetings of the Advisory Committee. Mr. Walsh acknowledged her frustration and stated that a fall 2020 meeting is being planned.

Public Comment

David Cartier, cHealthWorks Logistics: Wanted to speak on the current transportation challenges in the OPTN and to make some recommendations. There is little data on transportation, and the data that is available is inconsistent at best. Although sending test results has not been directly related to transportation, there are implications that there will be a number of other transportation challenges. Furthermore, it does not make sense to continue to manage a decentralized DSA-centric transportation solution when a centralized integrated transportation network is required. He recommends the creation of an independent national OPTN-focused transportation organization to improve the transportation metrics.

Mary Faith Harty had the following questions regarding COVID-19 patients:

- How is patient information and the usage of those organs being recorded and properly stored?
- Is there a data entry point with UNOS regarding COVID-19 transmission and usage. Who is going to be recording any kind of success rate regarding COVID-19 patients?
- What is the purpose of the usage, and how can one determine that someone has not been an asymptomatic patient or a patient that has been exposed but has not yet been determined by a nasal swab that they have COVID-19?

Thomas Kelly, Waitlist Zero: Stated his extreme disappointment in HRSA's recent proposed changes to the eligibility guidelines for the Reimbursement of Travel and Subsistence Expenses toward Living Organ Donation Program. He stated that raising the threshold from 300% of the HHS Poverty Guidelines to 350% is insufficient.

Adjournment

Mr. Walsh thanked everyone for their time and expertise and adjourned the meeting at 3:46 p.m.