

**OPTN Executive Committee
Meeting Summary
December 21, 2020
Conference Call**

**David Mulligan, MD, FACS, Chair
Matthew Cooper, M.D., Vice Chair**

Introduction

The Executive Committee (EC) met via teleconference on December 21, 2020, to discuss the following agenda items:

1. Welcome & Roll Call
2. December 1st Critical Comment on Kidney and Pancreas Allocation Policy to the Secretary (Review and Discuss)
3. Adjourn

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

1. Welcome & Roll Call

The Committee Chair welcomed all attendees to the meeting. The agenda was reviewed.

2. December 1st Critical Comment on Kidney and Pancreas Allocation Policy to the Secretary (Review and Discuss)

UNOS General Counsel, along with the UNOS Director of Policy and Community Relations presented issues raised in a critical comment submitted by Jones Day Law Firm on behalf of anonymous hospitals on 12/1/20 and sent to the Secretary of HHS on 12/2/20. The OPTN received a letter from the HRSA Administrator today, requesting input on specific items raised in the critical comment. A response is due no later than 1/4/21.

This critical comment is a process under the OPTN Final Rule by which anyone may submit a comment about the way the OPTN is fulfilling its obligations under NOTA and the Final Rule. The Secretary can ask for input from the OPTN about any critical comments received. The OPTN just received the letter from HRSA and will be distributing it soon. It includes specific questions about the policy that have already been analyzed by the Kidney Committee and Board, and was approved December 2019. The only new issue raised in the letter is the impact of the COVID on transportation. The critical comment states that the Final Rule requires the Secretary of HHS to publish kidney allocation policies in the Federal Register and refer them to the Advisory Committee on Organ Transplantation (ACOT). The Secretary has previously made his position on this clear in other litigation. Once the OPTN gives a response, the Secretary may reject the critical comment, give direction to the OPTN that might include revising policies, or take another action that he deems appropriate. The comment asserts that the Secretary should use this as a basis to direct the OPTN to permanently delay the kidney and pancreas allocation policy implementation due to bad faith on the part of the OPTN in the policy development process, that transportation during COVID makes implementing the policy problematic, and that the circle-based policy would harm patients and result in fewer transplants, longer times, and greater costs.

HHS is requesting the OPTN's consideration of the transition policy discussed by the Kidney Committee last spring; overview of the efforts to educate the public; and a description of OPTN's analyses regarding the impact on socioeconomic status. These issues will not be discussed at this meeting. The key issue to be discussed is the OPTN's plan to evaluate disruptions from COVID-19 around travel and the kidney allocation policy. The OPTN will work with the SRTR around some questions on the modeling and acceptance criteria.

Amber Wilk, UNOS Assistant Director of Research, presented on the COVID-19 effects on organ transplantation and travel. Publicly available data shows a decrease in waiting list registrations in mid-March 2020 at the beginning of the pandemic. This has rebounded close to pre-COVID numbers since July 2020. The number of inactivations from the waiting list increased significantly in March 2020, and has decreased to about 1% of the entire waiting list. A year-over-year comparison of kidney transplants up through December 2020 shows overall kidney transplants slightly down compared to 2019, but numbers are similar up until the pandemic started. Deceased donor transplants to-date exceeded 2019 by 1,181.

A year-over-year comparison of liver transplants up through December 2020 shows compared to 2019, liver transplants are up by about 80. Living donors have decreased by about 30 compared to 2019, but deceased donors are increased by 110 compared to 2019.

Deceased donors recovered by week in 2020 shows a dip in March 2020 with a rebound in the next 1-2 months. July 2020 showed the largest monthly volume of deceased donors ever recovered at 2,081 with a year-to-date increase of 1,246 compared to 2019. Both kidney and liver transplants week by week show similar trends, with a dip in March with a rebound April and May.

It was noted that despite COVID, and with the acuity circle broader sharing, there has been growth in deceased donor livers. The SRTR representative pointed out that the main argument of those initially in opposition of the liver allocation policy was a predicted decrease in volume of transplants by SRTR modeling due to the way acceptance was modeled, even though SRTR explained a change in behavior due to the allocation policy change could not be predicted accurately. The increase deceased donors (even during COVID), shows what the modeling can and cannot predict.

Looking at travel distance for deceased donor kidney transplants, median travel distance was 70 NM prior to COVID. During COVID overall median travel distance was 67 NM, which was broken down to 81 NM during the COVID shutdown period for two months at the beginning of the pandemic and 65 NM during the COVID stabilization period following those first two months.

Median travel distance for liver transplants was 90 NM pre-COVID. During COVID overall and with implementation of acuity circles allocation in 2019, the median was 148 NM, with 144 NM during the COVID shutdown and 151 NM during COVID stabilization. There was no change in percent of kidneys transplanted locally or within the donor service area (DSA) versus exported to a different DSA for transplant for the same time period in 2020 compared to 2019.

Adult kidney offer acceptance data from the SRTR website shows a dip in March 2020 with a sizeable rebound to numbers above pre-COVID. Similar data for adult livers also show a dip in March 2020, but since then, slightly lower acceptance rates pre-COVID compared to the same time period in 2019. Data from the SRTR website on distance between donor hospital and the transplant program the organ is offered to show various stratifications of nautical miles. There is a sizeable uptick in the median of accepted offers for 250 NM or more, which tapers back down and has remained constant since then.

Refusal reasons for kidney includes: transplant hospital operational issues and COVID-19 - OPO. Trends in declines due to these two reasons is similar to trends due to all declines. The number of overall declines has been stable since May 2020.

Policy monitoring during COVID poses some challenges, which include how the transplant community's response has changed over time; changes in metrics are not mutually exclusive between OPTN policy changes and the COVID-19 pandemic; and the amnesty emergency policy might affect monitoring of outcomes in the future. With a potential implementation date of acuity circles in February 2021 for kidney, there would be full six-month and one-year time periods during COVID, so it will be easier to compare pre and post policy. Liver was implemented right before COVID, so it is more difficult to compare pre and post policy changes.

The UNOS Director of Policy and Community Relations presented some of the modeling decisions that were made during kidney policy development. The SRTR Kidney-Pancreas Simulated Allocation Models (KPSAM) were used in the development. The critical comment related to modeling included that the impact on commercial flights was not considered. Mr. Connors explained that KPSAM does not have the ability to account for travel mode. However, the Committees did consider these factors during meeting deliberations. The critical comment also questioned the motives for doing a second modeling request. The modeling was discussed in detail in discussions leading up to the concept paper. It used data through 2017 under the DSA policy. Three factors to note in the acceptance model are donor characteristics, candidate characteristics, and a local indicator. The Kidney Committee understood that candidate time on dialysis and a local indicator would not be good predictors under acuity circles, so they chose to run a second level of modeling without those two characteristics. They also understood that due to limitations of the KPSAM, it assumes the organ is discarded offer #200, even though it would be possible for an organ to get past offer 200. Importantly, the second modeling request also used a different set of circle sizes and proximity points, along with the acceptance model changes.

KPSAM also does not account for travel mode, but travel and distance were ubiquitous throughout the deliberations. The proposal that went out to public comment had several different variations of circle sizes and distance was top of mind. SRTR modeling did assess socioeconomic status factors such as insurance status, median income by zip code, and urbanicity. The Committee also considered the Cumulative Community Risk Score (CCRS), which was modeled with liver allocation.

The Kidney Committee is aware of the critical comment and met earlier today to have discussion. General informal consensus was to move forward with implementation on the planned date, not seeing any reason to delay, despite the COVID-19 pandemic.

Summary of discussion:

Key points for Executive Committee discussion today are whether there are any reasons to delay the removal of DSA kidney and pancreas policies due to the impact of COVID-19 and whether there are any comments about the four COVID-19 emergency actions. One Committee member noted that travel has been affected by COVID-19, but it is not a reason to delay. Another Committee member agreed, noting that transplants have continued successfully throughout the pandemic.

The Policy Oversight Committee (POC) Chair made the EC aware of how the POC handled the work of reviewing the policies when the pandemic began. They spent a fair amount of time looking at which policies needed to be addressed emergently due to changes in practice caused by COVID. They focused on the goal of the policies and the change in condition or practice that was directly caused by COVID. A Committee member noted that the Kidney Committee did their due diligence in developing the policy. It went out to public comment twice and changes were made from the public comment feedback. From a patient perspective, the policy is being implemented to benefit more people. Another patient

representative on the Committee agreed, noting that the transplant community has learned how to modify their practices due to the pandemic and the data does not indicate a need to delay implementation.

The POC Chair noted that the acuity circles policy is intended to be transitional to continuous distribution to help move from categories to a composite score/points-based system. The EC Chair agreed that this is an important step toward continuous distribution. The Histocompatibility Representative agreed with previous comments that the data does not show a need to delay implementation.

Executive Committee members agreed that the perspective voiced in the critical comment did not seem to have any objective comments, but rather disagreement with a policy that has been thoughtfully developed through the system over several years. While COVID poses unique challenges in healthcare, data does not show a need to change the implementation timeline. There was agreement that the policy does not need to change and that the policy implementation should go forward.

Next Steps:

The OPTN will take into consideration the discussion from today's meeting and craft a draft response to the HRSA letter, which will then be shared with the Committee for review and approval.

3. Adjourn

The Executive Committee Chair thanked attendees for their time and participation. The meeting was adjourned.

Upcoming Meetings

- January 13, 2021 at 1-2 p.m. ET
- March 1, 2021 at 3-4 p.m. ET
- April 26, 2021 at 12-4 p.m. CT

Attendance

- **Committee Members**
 - David Mulligan
 - Matthew Cooper
 - Medhat Askar
 - Robert Goodman
 - Valinda Jones
 - Lisa Stocks
 - Jeffrey Orłowski
 - Christopher McLaughlin (HRSA)
 - Robert Walsh (HRSA)
 - Brian Shepard, OPTN Executive Director
- **SRTR Staff**
 - Ryo Hirose
 - Ajay Israni
- **UNOS Staff**
 - Craig Connors
 - Susie Sprinson
 - Chelsea Haynes
 - Jason Livingston
 - Amber Wilk
 - Liz Robbins
- **Other Attendees**
 - Alexandra Glazier, POC Chair