

**OPTN Executive Committee  
Meeting Summary  
April 26, 2021  
Conference Call**

**David Mulligan, MD, Chair  
Matthew Cooper, MD, Vice Chair**

## **Introduction**

The Executive Committee (EC) met via video conference on 04/26/2021 to discuss the following agenda items:

1. COVID Update, Data Review and Proposed Actions
2. Policy Oversight Committee Update
3. 2021-2024 OPTN Strategic Plan
4. Draft Federal Public Comment Submissions for Action

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

### **1. COVID Update, Data Review and Proposed Actions**

UNOS Research Staff presented an update on the COVID-related policies currently in effect.

In Policy 3, Modify Wait Time Initiation for Non-Dialysis Kidney Candidates, waiting times are tied to when candidates can register with qualifying criteria such as their GFR or creatinine clearance. The policy was set so that candidates who could not obtain labs due to COVID-19 restrictions could have a waiting time modification submitted by the center.

Adult kidney registrations week by week showed that the proportion of non-dialysis candidates has been just over a third of all registrations for the past several weeks. The number and percent of waiting time modification request forms submitted related to COVID-19 month by month showed there was a total of 31 or 75% of all modifications submissions in March. In February, it was just under 80% of all waiting time modifications.

Feedback on Policy 3 was requested from relevant stakeholder committees, the biggest stakeholder being the Kidney Committee. The feedback showed overall unanimous support for extending the policy through the summer of 2021. According to the data, the emergency policy is still being utilized. The feedback touched on issues that have been discussed by the Executive Committee, including how COVID-19 is impacting different areas of the country, how the policy is still helping with the backlog of patients who are having challenges getting registered for the waiting list, and issues with programs still dealing with understaffing. Also, the transplant programs would need a few months' notice prior to repealing Emergency Policy 3 in order to address kidney wait time and wait list management.

The Committee Chair pointed out that the new kidney allocation policy has been deployed, which could create changes in workflow management, patient flow management, and how to get patients listed. The priority has always been to be patient-centric and not disadvantage any patients as changes are being made.

In Policy 1, Updating Candidate Data During COVID-19 Emergency, programs can use the candidates' most recent labs, such as MELD score or LAS, to maintain their medical urgency status. Use of policy by week for the 2021 calendar year shows adult liver candidate use has been stable at about 1% or less week over week. Pediatric liver candidate use has been similarly low, with only three pediatric liver candidates using the policy this calendar year. Use of the policy for the 2021 calendar year by lung candidates shows a slight increase in the percent usage from December 2020, but still low at 2% in the past several months. There is no use by pediatric lung candidates. In addition, only five adult heart candidates have used the policy since its inception in April 2020, and none during this calendar year. The most recent data for the week of 3/29/2021 to 4/4/2021 shows a total of eight candidates using this policy, five adult liver and three adult lung patients. Since its inception, about 36 centers have reported using the policy for adult lung; and about 79 centers have reported using the policy for adult liver.

Feedback on Policy 1 was requested from stakeholder committees, including Heart, Liver, Lung and Transplant Coordinators, which revealed overwhelming support that the need for this policy is questionable, based on its overall low utilization, and utilization continues to decline. Repeal of the policy would restore the traditional organ-specific policy requirements for all candidates. Feedback suggested transplant centers would need 90 days' notice prior to repealing Emergency Policy 1 to update any outstanding candidate lab values.

The Committee did not have comments on Policy 1. A motion was made and seconded for the Executive Committee to repeal Policy 1.4.F, effective July 27, 2021. See Exhibit A for full details.

By a vote of 100% yes; 0% no; 0% abstained, it was

**RESOLVED**, that Policy 1.4.F: Updates to Candidate Data during 2020 COVID-19 Emergency, is hereby repealed, effective July 27, 2021.

A technical policy correction regarding Policy 2, Relax Data Submission Requirements for Follow-up Forms, was presented next. On 3/1/2021, the Executive Committee voted to repeal different provisions of Policy 2, but the policy language correction provided to the EC at the time of the vote was incorrectly presented. The correct language was then presented to the EC. The proposed correction is two-fold, consisting of approving a correction that will be effective immediately to restore the requirement related to the 30 day-reporting timeframe after the anniversary, as well as bring back the requirement that was approved in the Board action related to the Modify Data Submission Policies, which will extend the 30-day timeframe to 90 days, pending implementation.

The Committee did not have any comments on the correction. A motion was made and seconded.

By a vote of 100% yes; 0% no; 0%, it was

**RESOLVED**, that the changes to *Policy 18.1: Data Submission Requirements*, as set forth in Exhibit B, are hereby approved, effective April 26, 2021.

The most recent data trends show that LDF, TRF and PTM forms for patients or donors due through 3/31/2021 are now due 7/1/2021. Forms are no longer in amnesty status. A snapshot of the current form backlog was presented. About 6% of LDFs, 2.5% of the PTMs and 7.5% of TRF forms were still expected as of 4/9/2021. The median percent of expected forms by center is at less than 1% as of 4/9/2021. Ten centers have a total of 775 TRFs expected, which makes up about 44% of all the expected forms.

The update to Policy 4, Incorporate COVID-19 Infection Disease Testing into DonorNet, which was made permanent as of 1/27/2021, shows that since February 2021, 100% of donors have had their testing in the discrete infectious disease fields. Since the pandemic and since these reporting fields became

available through Policy 4, there are data in the discrete fields for 89% of all donors with 100% of donors being tested for COVID-19. There has been a total of 89 positive COVID-19 test results, reported for 64 unique donors. All positive results were communicated to transplant centers or made available in DonorNet prior to transplant.

The percent of matches with at least one COVID-19-related refusal reason per week for the 2021 calendar year by organ was presented. The majority of COVID-19-related refusals continue to be related to OPO or transplant hospital issues, but numbers are still much lower than they were at the onset of the pandemic. The percent of waitlist deaths by COVID-19-related by organ and week for the 2021 calendar year shows an increase in mid-March 2021 for lung, indicating that candidates removed from the waitlist due to death was about 66% related to COVID, but this represents two lung candidates, so low numbers overall. COVID-related post-transplant deaths are still mostly kidney recipients, but there is a decline in reported deaths since the end of January.

The Committee Chair asked if a patient was not seen during the pandemic, the center can report that and it will not count as absent data. Staff clarified that the forms just need to be submitted and validated, and the form could be validated by the center entering that the patient was not seen. The Vice Chair asked if centers are aware of their forms in amnesty, and staff clarified that centers were informed of their total forms in amnesty. The Chair thanked the community for working hard throughout the pandemic. The Chair noted that there were many changes and communications that have occurred since the onset of the pandemic, but still there were more transplants during the pandemic than have been done before. This is all due to the hard work of the transplant community to maximize the number of transplants.

Just to make the Committee aware, the Chair also noted that the notification for graft loss or patient loss moves back to the 14-day requirement from what was extended to a 30-day time period. In addition, there have been three or four probable donor transmissions of COVID-19. No known COVID-positive donor organs have been used for transplant into a patient, but there have been three or four instances where a donor was tested negative for COVID-19, but then later found to have been positive.

The Chair of the Ad Hoc Disease Transmission Advisory Committee (DTAC), Ricardo La Hoz, presented an updated summary of evidence on SARS-CoV-2. The EC previously approved a DTAC-sponsored summary of evidence document in February 2021, which included guidance on testing deceased and living donors for SARS-CoV-2 and also aid in organ utilization of donors with a history of COVID-19 both to minimize the risk of disease transmission and maximize organ utilization. The DTAC committed to review the document quarterly, but found additional evidence of three proven or probable transmissions to lung recipients in a particular scenario where the lung donor was only tested for SARS-CoV-2 in an upper respiratory sample, but not in a lower respiratory tract sample, and a transmission occurred. There was also a near miss in the same scenario.

Therefore, the update in the summary of evidence is to emphasize those three transmissions that have occurred. Testing a lung donor for SARS-CoV-2 in a lower respiratory tract decreases the risk of transmission. In addition, there is an international study addressing the time of surgery after SARS-CoV-2 infection, which has implications for living donors, so the section on timing of transplanting recipients with a history of COVID-19 in the document was updated and included a series of additional papers to the bibliography. The DTAC voted unanimously to approve the updated document. The EC Chair requested clarification on the DTAC's SARS-CoV-2 Summary of Evidence update, regarding whether it is talking about deep tracheal aspirate, which is like suctioning the endotracheal tube and getting a sample that doesn't require as much risk to the team doing a bronchoscopy and a bronchoalveolar lavage (BAL). In the past, using nasopharyngeal swabs and bronchial alveolar lavage as a deeper aspiration was discussed. When the DTAC discussed the implications of lower respiratory tract testing for lung donors,

several points came up: they were clearly alluding to the protection of both the OPO team and the surgical teams recovering organs. Many donors are being tested when admitted to the donor hospital. Optimal practice would be to test donors by an upper respiratory sample within a certain timeframe. If the test is negative, then proceed to obtain a lower respiratory tract sample if the donor is being considered for lung donation. An additional layer of complexity is the DCD donor and the compressed time to evaluate the DCD donor.

After receiving feedback from the OPO and Lung Committees, DTAC felt there should be some flexibility on the type of sample that would be used to test the donor for SARS-CoV-2. If only a BAL for all donors was proposed, there could be a potential risk for losing DCD lungs. Therefore, a good middle point was to have some flexibility in the type of sample. The evidence at this point does not suggest that a deep tracheal aspirate for non-lung donors will be necessary.

A motion was made and seconded for the Executive Committee to support the DTAC updated Summary of Evidence on SARS-CoV-2 with an update for specimens for lung donors, as presented by the DTAC Chair.

By a vote of 100% yes; 0% no; 0% abstained, it was

**RESOLVED** that the updated Summary of Evidence on SARS-CoV-2 is hereby approved, effective immediately.

The DTAC chair then presented the proposed COVID-19 Emergency Policy on Lower Respiratory Testing for All Lung Donors. The purpose is to address patient safety risk of COVID-19 transmission to lung recipients due to three cases in the span of three months of proven or probable transmission to lung recipients where the donor had no epidemiological risk factors or symptoms compatible with COVID-19, and the donors were tested by an upper respiratory tract sample. Additionally, there was one near miss in which the lungs were discarded after the test result became available. The last query for proportion of lung donors being tested for SARS-CoV-2 in a lower respiratory tract sample showed only 60% of lung donors met that criterion.

In addition, in one case of transmission to the lung recipient, COVID-19 was also transmitted to the lung transplant surgeon, highlighting the fact that obtaining a deeper specimen result may also be important for the safety of the recovery team.

The proposal is to require a lower respiratory tract sample to be tested for lung donors for SARS-CoV-2, with the results being available prior to procurement. A fair amount of feedback was received from the OPO and Lung Committees. Some feedback was about the availability of testing and the capability of testing. It became obvious that already some of the published cases were driving a change on OPO practices. Testing turnaround time was not a significant barrier. Another set of comments was about DCD donors and striking an optimal balance between patient safety and organ utilization. There was support from the OPO and Lung Committees to optimize the safety of lung recipients. Based on their feedback, the policy update would include a requirement for the test result prior to procurement, but not required for the test to be available for allocation, as well as flexibility on the definition of lower respiratory tract sample to account for DCD donations and so as not to risk losing DCD donors.

The proposed implementation is 30 days from EC approval to support all OPOs developing necessary testing partnership based on OPO Committee feedback. There are developing collaborations with the FDA on information on how the OPOs can close the gap in testing, have access to testing, partnering with other institutions, etc. There will also be a retrospective public comment in the Summer of 2021 and the emergency policy will expire in one year from implementation, unless the Board of Directors makes the policy permanent. The DTAC and OPO Committee are also developing a monitoring plan to

fully understand the implications of the emergency policy, but the guiding principle is really the safety of the lung recipients.

The proposal language includes a clear definition for a lower respiratory specimen, which is a sputum, tracheal aspirate, bronchial suction, bronchial wash, BAL, or lung biopsy. Under the "Required Deceased Donor Infection Disease Testing" section, it will include that infectious disease testing for all potential disease lung donors will be done using an FDA-licensed, approved, cleared, or emergency-use authorized lower respiratory specimen test for SARS-CoV-2 by nucleic acid test (NAT). Lower respiratory test specimen test results for SARS-CoV-2 by NAT must be available prior to lung procurement.

One Committee member expressed concern around the lower respiratory testing results being available prior to procurement, as it seems this policy would preclude OPOs from doing a rapid recovery or ex vivo perfusion case where the lungs have not been placed prior to them being procured and sent for further evaluation. This could happen with DCD donors, but also unstable donors.

The DTAC did consider different timelines, including having the test results prior to allocation or before implantation. They felt neither option was a good option because OPOs cannot control when lungs will be implanted. Therefore, they discussed test result requirement at the time of recovery. If the OPO thinks it is in the best interest to allocate lungs, they should proceed with ex vivo perfusion and those lungs will be perfused and the test will become available. Then the decision to transplant them or not will be made. The OPO could then claim that the policy deviation would be made because it was a DCD donor. The DCD was a point of discussion and striking a balance between safety and organ utilization was difficult to achieve, but the guiding principle continues to be patient safety so that in these particular scenarios, utilization of those lungs could be permitted and the impact of the policy will be minimized. The Committee member replied that when there is something in policy that is being knowingly violated, it puts the OPO in a bad position to be questioned down the line.

Another question was regarding inconclusive or inaccurate testing results. One OPO stopped doing bronchial lavage on every single donor because of an inordinately high number of inconclusive results, causing extreme delays in case times as much as 24 hours. Dr. La Hoz noted that there was feedback from many stakeholders, including representatives from other committees, around collaborations with donor hospitals doing a tracheal aspirate to test the donors for SARS-CoV-2, so the DTAC felt that not every single DCD would fall under the scenario where they would not have a SARS-CoV-2 test from a lower respiratory tract performed prior. In many instances, the testing was available prior to recovery, even for a DCD. Once again, striking a balance between safety and organ utilization was challenging. An ex-officio FDA DTAC member compiled all the available information for SARS-CoV-2 testing, which included the possibility that mucus from a tracheal aspirate could interfere with the testing. The information with all resources available for lower respiratory tract testing is available on the OPTN website.

The POC chair noted that the safety of transplants is on the transplant team, rather than the OPO, and that OPOs should not be in the position where they have to go forward with a planned noncompliance and then explain themselves. The Policy Analyst for DTAC reiterated the main reasons the DTAC felt that pre-procurement would be an appropriate balance between concerns from the OPO and Lung Programs side related to not wanting to make results tied to the organ offer because of a potential impact on utilization, while recognizing that there could be a tangential patient safety risk in the sense that if it's not back pre-procurement. As mentioned, there was a case in which the surgeon became infected as well, which also poses a patient safety risk. The Lung Committee agreed to definitely before transplant, but even earlier would be preferred, and the OPO Committee leaned towards definitely not before organ offer, but organ procurement was doable. The monitoring plan DTAC is developing will also help them to understand the implications of the policy.

A Committee member noted that OPOs should not have to decide between pursuing a specific class of donors or knowingly violating an OPTN policy that could alternately have some kind of secondary evaluation process prior to transplant in which the test results could be made available prior to the organ being utilized. The Committee member noted that there should be more flexibility in the language. Another Committee member agreed that OPOs or transplant programs should not be told that they can knowingly break policy, and supported changing the language to place some responsibility on the transplant centers.

One member of the Committee asked for clarification on how long a sample would be considered acceptable prior to recovery. They also asked if it would possible for samples to be taken from the nasopharynx and then potentially a deep tracheal aspirate at the same time or shortly after one another. Dr. La Hoz explained that the DTAC did not want to be too prescriptive on the timing of the sample, as requirements on sample timing could have negative implications. Dr. La Hoz emphasized that the monitoring plan is probably as important as the policy itself because it will help them understand which scenarios in which transmissions continue to occur, as well as the implications for lung donors.

Staff explained the options moving forward, which could include UNOS policy staff drafting new language for the EC to review later, or they could vote on the policy as written at this meeting. Committee members agreed that they would like to see revised language to the policy before making a vote.

After back and forth discussion by the Committee members, suggestions to language modification included lower respiratory testing for all lung donors be available prior to "lung transplant," rather than to "procurement," which would allow organs to be recovered prior to obtaining test results, but they would not be transplanted without results. The language could even be more specific to state prior to "initiation of lung transplant" or prior to "final acceptance for transplant," to address two scenarios of the organs have been accepted prior to recovery and the procedure is on order or the donor is being recovered and sent to be placed on an ex vivo device and the transplantability decision would be made later. UNOS staff clarified that the phrase "final acceptance" is not defined in policy, but rather "organ acceptance," which includes "pending" is used in the policy.

UNOS staff took time during the meeting to draft revisions to the emergency policy language so that the Executive Committee could vote on it during this meeting. In their draft, the definition will remain the same. The language under Section 2.9 was changed to "Lower respiratory specimen test results for SARS-CoV-2 by nucleic acid test must be available prior to pre-transplant of lungs." This would address the issue that OPOs might have certain circumstances, including DCDs, in which more time would be needed to evaluate the results and collaborate with the transplant programs, as well as the patient safety issues. One comment was that this type of information is now used for other acceptances of organs, such as kidneys are not accepted until kidney biopsy results are received, so the language change is very reasonable. A motion was made and seconded for the Executive Committee to approve the COVID-19 Emergency Policy: Lower Respiratory Testing for All Lung Donors.

By a vote of: 100% yes; 0% no; 0% abstained, it was

RESOLVED, that the changes to Policies 1.2: Definitions and 2.9: Required Deceased Donor Infectious Disease Testing, as set forth in Exhibit C, are hereby approved, effective May 27, 2021, and will expire on May 27, 2022.

## **2. Policy Oversight Committee Update**

The POC Chair presented the new projects recommended for approval. The first is a project proposal from the Minority Affairs (MAC) and Kidney Committees is to reassess the inclusion of race in the

estimated glomerular filtration rate (eGFR) equation and specifically to evaluate its use as a coefficient as it relates to listing wait time. This topic is of great interest in the transplant community, including organizations such as NKF and ASN, as it relates to listing wait time and racial disparities in access to transplantation. The Kidney and MAC will collaborate on this project. MAC has the bandwidth to take on this project. The sequencing of this project completion will be key for the Kidney Committee as they continue to work on continuous distribution, so this project needs to happen simultaneously or ideally before completion of continuous distribution. It would fall under Increase Equity in Access to Transplants in the Strategic Plan Alignment and would require a medium amount of resources to complete. It does not line directly with the strategic policy priorities, but is important due to the sequencing with the continuous distribution work.

The second project proposal from DTAC relates to additional data collection with the US Public Health Service (PHS) guidelines from 2020. It specifically looks to collect more data in order to identify trends in donors with specific risk criteria that impact patient safety and assess the impact of the OPTN policy alignment with the PHS guideline implementation in 2020. The data are often collected in text form, so this project would put the data in a format that allows for non-manual reports and analyses. Data Advisory, Ethics, Operations and Safety, OPO, Pediatric Transplantation, Transplant Administrators, and Transplant Coordinators would be collaborating committees. DTAC has the bandwidth to complete the project at this time. It falls under Promote Living Donor and Transplant Recipient Safety in the Strategic Plan Alignment and will require programming work, so a large amount of resources. It is not part of the strategic policy priority work, but is important regardless.

The third project proposal from the Liver & Intestinal Organ Transplantation Committee is part of their ongoing review of certain diagnoses and to provide additional guidance for consistency. The goal is to systematically be reviewing six to eight diagnoses every six months, beginning with hepatocellular carcinoma, ascites, gastrointestinal bleeding, hepatic encephalopathy, hepatic hydrothorax, and primary/secondary sclerosing cholangitis. The POC supported the project as an ongoing way to ensure good guidance, clarity, and consistency, and recommended incorporating the review of pediatric guidance in future Liver Committee efforts. There are no collaborating committees. This is a small project in terms of resources necessary and the sequencing is important, so the Liver Committee felt they have the bandwidth to take on the work. It is not part of the strategic policy alignment.

The fourth is a project proposal, as well as a special public comment request from the Lung Committee is to refine lung data fields. The proposal is intended to address gaps in policy. The OPTN staff conducted a gap analysis of allocation policies and the way data are collected and used for allocation in UNet. Several areas needed clarification, especially when there will be implementation in conjunction with the changes that are going to be made to the Lung Allocation Score (LAS) just approved by the Board in December 2020. Although the Lung Committee is working on other projects, this project is important to get done, and for it to go out for the special public comment period, so that the timing creates the most efficient project work possible. The project falls under Increase Equity in Access to Transplants in the Strategic Plan Alignment. It is not part of the strategic policy priorities.

The Lung Committee asked that the Refine Lung Data Fields project as noted above go out to a special public comment timeline of April 27 to May 27, 2021, with Executive Committee consideration in July 2021. This will help make sure that the placement and sequencing of this project is in its most effective moment, which is when the other changes to lung allocation are being made. The recommendation is for the proposal to go out to public comment in May so that it will be ready for consideration in July, and that the change can be made at the same time as the lung allocation changes scheduled for the fall.

The final action item is the POC's proposal of the creation of an Ad Hoc Multi-Organ Transplantation Committee. The purpose of the committee would be to advance policy development on the Strategic

Policy Priority of multi-organ transplantation. The proposal specifically is to create this committee and committee leadership from the existing organ-specific committees and other specific committees to do the cross-committee work and ensure unified policy development on how multi-organ transplantation relative to single-organs transplantation is going to work as continuous distribution moves forward. The POC members considered whether they could complete the work themselves, but felt the work needs to be far more granular than they could accomplish, given the other workload of the POC. They also felt the leadership that are developing the continuous distribution work plan needs to weigh in on the multi-organ transplantation component.

The previous multi-organ transplantation work has been general work from the OPO Committee and has not been about specific organ combinations. The Ethics Committee came out with a white paper with principles of multi-organ transplantation. The POC identified multi-organ transplantation as an area that would benefit from being identified as being Strategic Policy Priority because it requires so much cross-committee work and because it is a large amount of work that has been needed for a long time. The first steps were the framework from the Ethics Committee, the general policy from the OPO Committee, and now comprehensive specific policies on multi-organ transplantation relative to single-organ transplantation need to be developed. The coordination needs to happen now, so this will prevent inconsistent decisions on how multi-organ transplant is handled, as compared to a single-organ transplant.

The proposed charge of the committee was reviewed and many of the OPTN committees will be represented in the work, but DAC and Histocompatibility Committee involvement will only be needed at certain times in policy development. The proposed project map for the committee, including the combinations of work at the same moment in time that continuous distribution is being developed for each organ type, was also reviewed.

#### Summary of discussion:

The EC Chair inquired as to any feedback regarding the PHS Guideline to require that all transplant centers keep 10 years of living donor samples. The POC also expressed concern over this, as well as the 72-hour testing requirement on OPOs and potential increased costs without additional safety benefit. It was clarified that the 10 years was based on the OPTN requirement to store deceased donor samples for 10 years. Any evidence from OPTN that demonstrates a different time period is better would be important. Frank Holloman from HRSA remarked that the department is in a state of transition and COVID-19 has been first priority, but it will continue to be monitored, and they will provide additional information as soon as possible. Chris McLaughlin from HRSA noted that the OPTN should provide a recommendation.

There were no further questions regarding any of the other project proposals. A motion was made and seconded for the Executive Committee to approve all new committee projects, as recommended by the POC.

The results were as follows: 100% yes; 0% no; 0% abstained.

A motion was made and seconded for the Executive Committee to approve the release of the Lung Committee's Refine Lung Data Fields project proposal as a special public comment, as recommended by the POC.

The results were as follows: 100% yes; 0% no; 0% abstained.

The EC Chair commented on the POC's recommendation to create an Ad Hoc Multi-Organ Transplantation Committee. He felt this may be an ongoing, rather than an ad hoc committee going



forward, but is definitely important work at this time. There was support for the committee creation as a whole, as well as agreement that the work is long overdue.

A motion was made and seconded for the Executive Committee to approve the creation of the Ad Hoc Multi-Organ Transplantation Committee, as recommended by the POC.

By a vote of 100% yes; 0% no; 0%, it was

**RESOLVED**, that creation of an Ad Hoc Multi-Organ Transplantation Committee, including representatives from each organ-specific committee, the Organ Procurement Organization Committee and the Pediatrics Committee, not to exceed 18 members, is hereby approved, effective immediately, and shall dissolve on June 30, 2024.

### **3. 2021-2024 OPTN Strategic Plan**

The OPTN Executive Director presented the details of the proposed 2021-2024 Strategic Plan, which has been in development for close to a year. The EC has received all the specific public comments regarding the Strategic Plan. The EC also received the draft of the Strategic Plan, which includes specific edits following public comment, but the EC will make the final proposal to the Board.

The comments are overwhelmingly in favor of adopting a Strategic Plan. There were some questions about explaining acronyms and promoting more readability for community members. There were a number of comments on metrics. There were multiple comments regarding the tension between increasing transplants and improving outcomes, which is true, but it is appropriate to have both those goals and have a metric that allows people to make the best use of the organs are available. There was also discussion of increased patient input, as well as tools for patients around living donation and tools about how to understand the metrics. There was support for efficiency initiatives, some of which are underway and that the POC is leading. There was support for linking the previous efficiency goal into the increase transplants goal. There was a request for an increase in emphasis on living donation. There was no discussion about any necessary additional patient safety activities, but there were suggestions that some of the resources for that should be reallocated to outcomes projects.

There were a handful of comments around resource allocation, including concern over the message being sent about more time being spent on increased transplants than improved outcomes. That message might encourage riskier behavior. However, all the goals are important and how much time is spent on new projects in the future do not make one goal more valuable than another goal. There was concern that with continuous distribution, the 30% allocation to equity would not be enough.

There were suggestions out of the scope of OPTN, such as establishing organ recovery centers, providing incentives to centers and OPOs that collaborate well, and eliminating five-star metrics. There were also suggestions on things that have already been addressed, such as mentorship for high KDPI kidneys, which sounds a lot like COIIN, and educating patients on using social media, which the Ethics Committee just published guidance through a white paper on.

The OPTN Executive Director then reviewed with the EC members the OPTN Strategic Plan draft point by point. First was Goal 1: Increase the number of transplants. One point received today was to add a clarification on DCD organs in the area of heart transplantation. Minor changes to language surrounding mechanical preservation were changed. Also, living donation itself was made an initiative, with a few items under it, and not just an item on kidney paired donation.

Goal 2: Provide equity in access to transplants, included the patient suggestion about increasing involvement through the policy development process. The Patient Affairs Committee's (PAC) suggestion was more precise and included increased numbers of patients on every committee and every project.

PAC also called out the efforts to increase data collection and using non-OPTN data in a special project with HRSA funding that links OPTN data with outside data enhance the knowledge of people's access to the waitlist.

Goal 3: Promote living donor and transplant recipient safety, is the safety goal where the message from public comment seemed to be to stay the course and not undo or add any initiatives or requirements. The draft removes 5% of the resources from this goal to the outcomes goal, which would still need to be approved by the EC. Two comments were around members' feedback from the MPSC experience, as well as increasing the community's willingness to participate in self reporting, which kicks off many of the improvement projects. There were many comments on the metrics, but no comments on the safety aspects.

Goal 4: Improve waitlisted patient, living donor, and transplant recipients outcomes gets a little bit higher resource allocation at 15%. At the strategic plan level, the draft does not specify how the metrics are enforced, how much weight the MPSC should put on each one, and does not specify how they should be calculated. But if the additions on the draft are adopted, it would convey the message that the MPSC should think about one-year quality of life outcomes, as there is often disagreement that one year is not enough. Based on a PAC recommendation, there is some earlier language about helping patients understand metrics and what the means about the programs they're considering, and what the tools for living donation might look like. The MPSC is already broadening its scope towards a range of ways to measure transplant success, rather than trying to tie all the metrics into a single number that represents everything there is to know about a transplant center.

#### Summary of discussion:

There was a comment that developing policies to allow deceased donor kidneys to begin kidney paired donation chains is a great idea. One question was whether this would need to go through the OPTN or the other paired donation process. A deceased donor kidney is used to fire up a chain as the first donor in a series of incompatible pairs and is a great way to instigate more transplants that have these incompatible pairs. It was clarified that the likely outcome is that if deceased donor kidneys is involved, that will be an OPTN activity and there will be no place to divert those, but whether to include this or not will be under the direction of the Kidney Committee.

The Committee felt the Goal 2 of the Strategic Plan was very responsive to PAC's comments and involving patients in the key processes helps on both sides with education and awareness, but also for the transplant community to learn the patients' perspectives.

The EC Chair commented that the points added under Goal 4 are important. The definition of success has changed. It used to be one year graft in patient survival, but it's now in the high 90th percentile range. There is a lot of opportunity for patient-reported outcomes. It will be important to look at how transplant success is defined and the opportunity to innovate without hampering the one year graft or patient survival. The EC might consider adding a definition of a better metric or better composite of metrics for determining transplant success. The OPTN Executive Director clarified that these metrics are for the transplant community. Something could be included now and then staff could put together what the specific metric would be or the Committee could work on the broader metrics and then come back and adopt one of those broader things as part of the list for tracking. Longevity and quality of life have been added, and one suggestion was to add that in the form of an initiative, rather than a metric, since it has yet to be defined.

One Committee member who had a transplant seven years ago stated that over time, transplant recipients can develop skin cancer, diabetes, or a number of others things. In general, these are the types of metrics that are included in Goal 4, but the Committee needs to decide which of those

specifically will be useful. Some may not be able to be used to address transplant center performance, but might be a good research project and good for future decision making for other policies. Looking at quality of life and how fully the patient is restored in all facets of life, in addition to one year graft survival, is important.

A motion was made and seconded for the Executive Committee to support the recommendation of the Executive Committee to the Board of Directors to approve the OPTN Strategic Plan for 2021-2024, as presented.

Results were as follows: 100% yes; 0% no; 0% abstained.

#### **4. Draft Federal Public Comment Submissions for Action**

UNOS staff presented two draft letters that the Committee will send to the federal government via the Federal Register, based on two public comment periods.

The first letter is related to transplant procedures with living donors and coverage of those that are in service. The proposed regulation would allow the VA to conduct living donor explants and cover their care and services before and after the procedure in connection to the veteran's transplant. Points to be made to the VA include support for the goals of the proposed rule; a reminder that when the VA enters into an agreement with a non-VA facility, they should be sure that the non-VA facility is approved for the recovery of organs from living donors; and that reporting and monitoring requirements for solid organ and bone marrow transplants are different.

One committee member commented that it wasn't that long ago that the VA acknowledged living donor transplant as being acceptable for veterans to undergo, so it's exciting to be able to collaborate with them in order to increase the opportunity for transplant for the veterans. There were no questions or additional comments from the Committee on the first letter.

A motion was made and seconded for the Executive Committee to approve submission to the Federal Register the response to the April 20201 OPTN response to the U.S. Department of Veterans Affairs proposed rule, *Transplant Procedures with Live Donors and Related Care Services*, pending non-substantive and/or clerical edits subject to the President's approval.

Results were as follows: 100% yes; 0% no; 0% abstained.

The second letter is a response to the U.S. Agency for Healthcare Research & Quality (AHRQ). It is a request for information, so not a proposed rule or forthcoming regulation. AHRQ posed a series of questions in their request for information on the use of clinical algorithms that have the potential to introduce racial/ethnic bias into healthcare delivery. The OPTN response incorporated feedback from the MAC and Kidney eGFR Work Group and includes the definition and a high-level overview of the eGFR and waiting time in kidney policy; clarifies that the eGFR is not required in OPTN policy; and points to additional research and resources that have come out recently such as the APOLLO study and recent NKF/ASN piece.

The EC Chair reiterated how important it is they make sure they are doing everything possible to not create any racial or ethnic bias or inequities in anything they do. There were no questions or additional comments from the Committee on the second letter.

A motion was made and seconded for the Executive Committee to approve submission to the Federal Register the response to the April 20201 OPTN response to the U.S. AHRQ's request for information, pending non-substantive and/or clerical edits subject to the President's approval.

Results were as follows: 100% yes; 0% no; 0% abstained.

### **Upcoming Meeting**

- Monday, June 14, 2021, 10-11 am ET

## Attendance

- **Committee Members**
  - David Mulligan
  - Matthew Cooper
  - Maryl Johnson
  - Jeff Orłowski
  - Ricardo LaHoz
  - Alex Glazier
  - Lisa Stocks
  - Atsushi Yoshida
  - Shannon Taitt
  - Frank Holloman
  - Christopher McLaughlin
  - Robert Goodman
  - Susan Tlusty
  - Medhat Askar
- **HRSA Representatives**
  - Christopher McLaughlin
- **UNOS Staff**
  - Laura Cartwright
  - Matt Prentice
  - Rebecca Murdock
  - Chelsea Haynes
  - Abby Fox
  - Susie Sprinson
  - Roger Brown



# Exhibit B - Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Language that appears earlier in the relevant section that is unaffected is represented by brackets and ellipses.

1           **RESOLVED, that the changes to *Policy 18.1: Data Submission Requirements*, as set forth below,**  
 2           **are hereby approved, effective April 26, 2021.**

3  
 4           **18.1 Data Submission Requirements**

5           Members must submit data to the OPTN according to Table 18-1.  
 6  
 7

Table 18-1: Data Submission Requirements

<b>The following member:</b>	<b><i>Must submit the following materials to the OPTN:</i></b>	<b><i>Within:</i></b>	<b><i>For:</i></b>
Transplant Hospitals	Organ Specific Transplant Recipient Follow-up (TRF)	<i>Either of the following:</i> <ul style="list-style-type: none"> <li>• <u>30 days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure</u></li> <li>• 14 days from notification of the recipient's death or graft failure</li> </ul>	Each recipient followed by the hospital

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 9           [...]

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 11           **FURTHER RESOLVED, that the changes *Policy 18.1: Data Submission Requirements*, as set forth**  
 12           **below, are hereby approved, effective upon implementation of the *Modify Data Submission***  
 13           ***Policies* proposal approved by the OPTN Board in December of 2019.**

14  
 15           **18.1 Data Submission Requirements**

16           Members must submit data to the OPTN according to Table 18-1.  
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Table 18-1: Data Submission Requirements

<b>The following member:</b>	<b>Must submit the following materials to the OPTN:</b>	<b>Within:</b>	<b>For:</b>
Transplant hospitals	<i>Organ Specific Transplant Recipient Follow-up (TRF)</i>	<i>Either of the following:</i> <ul style="list-style-type: none"> <li>• <del>30-90</del> days after the six-month and annual anniversary of the transplant date until the recipient's death or graft failure</li> <li>• 14 days from notification of the recipient's death or graft failure</li> </ul>	Each recipient followed by the hospital

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## Exhibit C

**RESOLVED, that the changes to *Policies 1.2: Definitions* and *2.9: Required Deceased Donor Infectious Disease Testing*, as set forth below, are hereby approved, effective May 27, 2021, and will expire on May 27, 2022.**

## 1.2 Definitions

### Lower respiratory specimen

A sample taken from the respiratory system within the trachea or below. Sputum, tracheal aspirate, bronchial suction, bronchial wash, bronchoalveolar lavage (BAL), and lung biopsy are considered lower respiratory specimens.

## 2.9 Required Deceased Donor Infectious Disease Testing

The host OPO is responsible for ensuring that *all* of the following infectious disease testing is completed in Clinical Laboratory Improvement Amendments (CLIA)-certified laboratories, or in laboratories meeting equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS):

1. Blood and urine cultures
2. Infectious disease testing for all potential deceased organ donors using FDA licensed, approved or cleared tests, as listed below:
  - a. HIV antibody (anti-HIV) donor screening test *or* HIV antigen/antibody (Ag/Ab) combination test
  - b. HIV ribonucleic acid (RNA) by donor screening or diagnostic nucleic acid test (NAT)
  - c. Hepatitis B surface antigen (HBsAg) donor screening test
  - d. Hepatitis B core antibody (total anti-HBc) donor screening test
  - e. Hepatitis B deoxyribonucleic acid (DNA) by donor screening or diagnostic nucleic acid test (NAT)
  - f. Hepatitis C antibody donor screening test (anti-HCV)
  - g. Hepatitis C ribonucleic acid (RNA) by donor screening or diagnostic nucleic acid test (NAT)
  - h. Cytomegalovirus (CMV) antibody (anti-CMV) donor screening *or* diagnostic test
  - i. Epstein-Barr Virus (EBV) antibody (anti-EBV) donor screening *or* diagnostic test
  - j. Syphilis donor screening *or* diagnostic test
  - k. Toxoplasma Immunoglobulin G (IgG) antibody test

Donor samples for all required HIV, HBV, and HCV testing must be obtained within 96 hours prior to organ procurement.

3. Infectious disease testing for all potential deceased lung donors using an FDA licensed, approved, cleared, or emergency use authorized, lower respiratory specimen test for SARS-CoV-2 (COVID-19) by nucleic acid test (NAT)

Lower respiratory specimen test results for SARS-CoV-2 by nucleic acid test (NAT) must be available pre-transplant of lungs.