OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

OPTN Executive Committee
Meeting Minutes
April 12, 2019
Chicago, Illinois

Sue Dunn, Chair

Introduction

The Executive Committee met in Chicago, Illinois on 04/12/2019 to discuss the following agenda items:

1. Welcome
2. New OPTN Contract
3. OPTN/DTAC Recommendations to the CDC on Definition of Increased Risk Organs
4. Organ Center Kidney Accelerated Placement Concept (KAP)
5. Policy Corrections and Clarifications
6. Geography Projects Update
7. Board Report Preview from the Ad Hoc Systems Performance Committee (SPC)
8. Policy Oversight Committee (POC) Update
9. OPTN Budget Preview
10. OPTN IT Update
11. Adjourn

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

1. Welcome

The Committee Chair welcomed all attendees to the meeting.

2. New OPTN Contract

The new OPTN contract provides more clarity on when meetings convene to represent OPTN as opposed to convening as UNOS, as well as clarity on cultural behaviors of the OPTN organization. For example, the slide deck is OPTN-specific and OPTN meetings will be advertised as OPTN. The contract calls for specific orientations and attestations from Board members to understand how the OPTN role is different and distinct, and what their obligations to the OPTN are. Committee members will hear more directly from HRSA and there will be HRSA presentations at upcoming Board meetings.

The new contract was designed under what is called a Performance Work Statement, which looks more at outcomes and focuses on innovation and improvement of the OPTN operations. It gives UNOS more flexibility than in the past to get things done, which will benefit OPTN overall. There will be more efforts with data collection and with COIIN collaboration. The contract will place a greater emphasis on the role and responsibility of the OPTN Board itself, particularly in meeting the requirements of NOTA and OPTN. System operations will be clarified as to which committees will have oversight over specific operating functions, as well as expectations from the Board itself. Board members will have dual OPTN and UNOS responsibilities. The new contract will allow for more direct relationships with OPTN itself. UNOS is committed to adding more resources as the role of OPTN grows, as well as improving communication.

For OPTN Board Meeting agendas, OPTN will try to do a better job of grouping items, so that all OPTN committees will be on Sunday afternoon, allowing for an earlier start on Day 2 with an all-day Board Meeting. UNOS work will not be interlaced with OPTN business.

3. OPTN/DTAC Recommendations to the CDC on Definition of Increased Risk Organs

The CDC will issue new guidelines for “increased risk organs” and wants OPTN feedback prior to public comment. The Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) met with the Secretary of Health and Human Services to look more broadly at a CDC request to consider changing the framework that Public Health Service (PHS) increased risk guidelines are based around. This began about a year ago when there was question about whether PHS was as efficient as it could be. ACBTSA is made up of members of the blood and tissue community and solid organ transplant community.

The past chair of Ad Hoc Disease Transmission Advisory Committee (DTAC) presented today on PHS guidelines, how well it performs looking at CDC data, and how things might be improved. The recommendations come from consensus opinion of DTAC, but hold no weight. However, if the subcommittee approves the recommendations, PHS will come out with more formal recommendations that OPTN will implement.

The DTAC Chair will be asked to answer four questions.

1. Is a new term needed to replace the term “increased risk donor?”

   A few years ago the PHS term “high risk donor” was changed to “increased risk donor.” The concern was that “increased risk” caused bias against organs that proportionally the risk is actually low. After OPTN consulted with a behavioral psychologist, they came up with no consensus for an alternate term.

   There are also cognitive biases that lead people to reject organs. One is base rate fallacy, which is placing more emphasis on specific information compared so that the focus is on “increased risk,” rather than the focus on organ quality. A second is negativity bias, which when all things are equal, someone weighs a greater amount of influence on things that appear negative. A third is stigma of disease, such as the stigma for HIV and hepatitis that widely exists still. The final is a concept of zero risk bias, which is the preferential desire to completely eliminate one risk at the expense of other things that may in fact be worse. In this case, people will reject an increased risk organ offer at the expense of getting an organ offer at all. All of these cognitive biases subconsciously affect the way people choose certain things.

   OPTN’s suggestion back to the advisory committee is that they can come up with more neutral terms, at least to make the choices less threatening. The move from “high risk” to “increased risk” was an improvement, but it still adds more bias than needed.

   One suggestion was when one is faced only two options of increased risk or not, that implies extra difficulty. This is seen in commercial advertising all the time. The addition of a third option diminishes the negative bias towards the second option quite substantially. The way it could be presented is someone who has no risk, someone who has an identified behavioral risk according to PHS, and a third category of an organ that requires further testing because there has been a positive test. Therefore, the discussion with a transplant recipient with three options is very different because people are much more reassured about PHS type B than what they currently are.

2. Should donors continue to be identified based on risk factors for HIV and hepatitis?

   The audience here includes a lot of tissue, pathology and blood bank colleagues, and their understanding of risk tolerance is a little different from that of the transplant community. The transplant team has a responsibility to educate patients about infections, and while the risk of difficulty from transplantation of HIV or hepatitis is less, most people still feel that the three viruses should be separated out when discussing

infectious risk. For example, better treatments for hepatitis C exist, but they're not yet used by the entire transplant community. In addition, there is no expectation for every transplant center to have HIV or hepatitis expertise.

3. Should time be shortened from 12 months?

   Currently, behavioral risk factors are measured within a 12-month time period, but when this first began, 12 months seemed logical due to the lack of NAT testing at the time. Now far greater than 99% of all donors get Triplex NAT testing for all of these viruses, and that has decreased the window of possibly missing infection. Based on CDC data, this window can be comfortably shortened to 30 days or probably a lot less. The 30 days for behavioral risk factor becomes both a manageable piece of history, but also something that should mean that fewer people are stratified as increased risk when practically they don't have that risk.

   Risk curves showing the residual risk of a test being incorrectly negative were shown. When you run a donor test, what's the chance of a negative result when there is actually low-level viremia present? Those who inject drugs have the highest risk of this occurring. For HIV specifically, the window period with NAT testing has brought the risk down to less than 1 in a million within a 10-day period. For hepatitis C, the risk is the same, but within a 7-day period. Hepatitis B is the only one where that risk is a little bit longer. The risk falls from 1 in 1000 to 1 in a million between 10 and 30 days, but hepatitis B is also the least common of all these viruses. From this data, the conclusion was that 12 months is longer than needed, and that timeline can be cut back to a month.

4. Are there specific risk criteria that could be eliminated or revised?

   Currently, a donor that is identified through OPTN as increased risk, OPOs are not required to give a reason for the increased behavior. This makes it difficult to statistically look at all the different behavioral risk factors. Statisticians had to go back and manually sift through a random sample of cases. A 10% sample of deceased donors from 2018 classified as increased risk was looked at to understand what their risks were.

   A map and bar graph was shown that demonstrated increased risk categorization as being higher with the opiate epidemic in regions 2, 3, 5, 10 and 11, where commonly these days it's 25% to 30%. The curves are pretty similar, indicating a good random selection. For statistical confirmation, this was thought to be an accurate sampling technique.

   The majority of increased risk donors only identified a single risk. About two-thirds of patients had one behavioral risk that they identified. Some people had many behavioral risks. The indication of what those risks were was really interesting; 16% of increased risk donors were intravenous drug users and 15% were incarcerated, clearly making the greatest number of behavioral risks that we identify in our donors. When looking at the 179 increased risk donors with one criterion only, the most common is incarceration, although hemodialysis and hemodilution make up about 1 in 7 of the cases as well.

   When looking at hemodialysis and hemodilution, these are included in the current PHS because historical data did support the fact that hepatitis C transmissions were occurring in dialysis settings and there have been issues in the past before universal NAT testing was put into place where hemodiluted samples led to false negative serologic assessments of donors.

   Between 2008 and 2018 there were no transmissions of HIV, hep C or hep B due to hemodialysis or hemodilution. Hemodilution itself was put in the increased risk category

for events that occurred more than 10 years ago. Also, there is good CDC statistical data that supports far fewer transmissions of hep C occurring in dialysis. With all of that, it made us begin to think that both of those categories could be taken away.

Pediatrics are specific as well. Pediatric organ use is different when discussing PHS increased risk. Pediatric groups are more reluctant to use increased risk donors for a lot of reasons, but of all deceased donors in 2018, a small number were less than age 12 and 60% were due to hemodilution as the sole criterion. Therefore, without a recent transmission event, which is also unlikely with NAT testing, maybe this is also something that could be changed.

The largest impact on decreasing the numbers of donors that fall under increased risk donation despite really having essentially no risk of transmission event would be to change the timeline. OPTN agrees that the 12-month timeline should be cut shorter to 1 month and would be comfortable with eliminating hemodialysis and hemodilution, particularly for pediatrics, although other stakeholders need to weigh into that, particularly the blood community with hemodilution may push back.

In conclusion, OPTN strongly applauds PHS for considering the amount of workload that it will take to make changes to increased risk donor criteria and their willingness to reconsider the current language and guidelines. There is worthiness to continue having risk assessment for HIV and hepatitis to maintain both transparency, public trust, and ensure necessary followup of recipients. There is a way of changing the name to a more neutral term that helps people understand risk. There is an opportunity to reduce the 12-month timeline and the majority of the committee felt that 1 month was safe, but this could be debated further as the process moves forward. The removal of hemodialysis and hemodilution, especially in pediatrics, should be considered.

DTAC's recommendations will lead to the larger group being able to discuss whether they should give approval for CDC/PHS to move forward with a rewrite.

One Committee member agreed with all the proposed changes, but was concerned about the hemodilution issue because there has been a hemodilution issue of unexpected blood types going to transplants. She was unsure if NAT testing would be enough for them to be confident that hemodilution is not an issue in terms of disease transmission.

From the NAT testing perspective, it would be difficult for a truly viremic person to have a negative result. But it would stretch the eclipse window where the test is negative despite there being recently-transmitted infectious blood in the donor. Statistically, with the exception of hep B, HIV and hep C risk is less than 1 in a million within 10 days, so even 30 days is conservative, which would help with the hemodilution argument that if someone's blood volume was diluted by even a third, HIV and hep C would run less than 1 in a million at a month. CDC and the blood community will probably not tackle hemodilution.

A motion was made and seconded for the Executive Committee to support the DTAC sharing the above recommendations with HHS on behalf of the OPTN.

A voice vote was taken and the results were as follows: 100% yes; 0% no; 0% abstained.

4. Organ Center Kidney Accelerated Placement Concept (KAP)

Data summary:

The KAP concept was previously presented at an earlier Executive Committee meeting meeting, but the UNOS Research Department has completed its data analysis and today will present the full plan.

Organ Center data from 2017 indicates 2,100 potential kidney donors for non-mandatory national shares. The median KDPI was 80 and the amount of time to place ranged from 0.5 to 21 hours, but if adding OPO time, could be up to 56 hours. Overall placement rate was 28%, but for extremely hard-to-place KDPI 80 and above, it was less than 15%.

The ultimate proposal is accelerate the offers of hard-to-place kidneys first to programs more likely to accept them and with a history of accepting them while continuing to offer them to all programs on the national match run.

A graph was shown looking at the expected kidney yield for donors of the non-mandatory national share matches broken up by donor KDPI and colored by the number of kidneys actually transplanted. The Organ Center not only sees a lot of high KDPI donors, but few kidney transplants come from these donors. Some matches need to be offered to many, many candidates, causing increased cold ischemic time, whether or not the kidneys are transplanted in the end. Essentially, the goals are to decrease placement time and to convert the blue to orange and green by lowering the number of candidates that need to be offered to at the onset.

Which matches will be part of the accelerated placement process? Kidneys are first offered to high CPRA and zero-mismatch national offers; the OPOs look at local DSA offers; the OPO or Organ Center will offer regionally; and then the Organ Center offers at the national level. Therefore, this will look at a subset of kidneys offered and refused at the local and regional levels and come to the Organ Center as national non-mandatory share offers.

Certain criteria will be used by transplant programs to further narrow the eligible kidneys and match runs. In addition to national non-mandatory share offers, donors with high KDPI (80 and above) will be looked at. This allows for more potential for positive benefit and positive change than negative consequences. Triggers are two endpoints: reaching the national classification and being offered to all candidates at local and regional levels, and being part of the approximately 50% of donors that come to the organ center with the highest KDPI. This aligns with NKF recommendations fairly well.

For transplant program to qualify once the accelerated placement process has been triggered, first offers will be to transplant programs that have accepted and transplanted a like organ. Donors will be identified that have characteristics that differentiate acceptance of marginal kidneys based on prior literature and a research analysis. Transplant programs will quality based on looking at all kidney transplants that have performed in the prior 2 years, which will be updated monthly. Therefore, all transplant programs will be potentially eligible to receive accelerated offers on each match. Surgeons who move centers and perform a transplant with the particularly donor characteristics identified will be rolled into qualifying for the next month. Transplant programs that have transplanted a kidney from a donor with the same or worse characteristics as the current donor will also qualify. This will be determined for each specific match in real time.

As part of the analysis that led to the donor characteristics that are part of the qualification process, preliminary univariate analyses were done to narrow down potential donor characteristics to consider looking at predictors of acceptance for the national non-mandatory share, high KDPI kidney donors. The characteristics considered include hepatitis B and HBV. Those were narrowed down to seven characteristics: KDPI, donor age, donor peak serum creatinine, history of diabetes, history of hypertension, history of IV drug use, PHS increased risk, and DCD status. The seven were tested in a multiple logistic regression model and did a model selection process to determine if they were predictive of acceptance for these donors. Based on hypothesis testing, the seven characteristics were narrowed to six, with history of hypertension and PHS increased risk being removed.

As an example of how the process will work, if a given donor has been offered to local and regional candidates and refused and comes to the Organ Center as national offers for this donor, the transplant programs that will appear first for this match are those that have transplanted at least one kidney from a donor that has a KDPI or 89 or high, age 45 or higher, has peak serum creatinine of 0.67 or higher, has a history of diabetes, is DCD, and may or may not have had a history of IV drug use. KDPI is a strict threshold, whereas age and peak serum creatinine have a buffer to account for a center accepting a kidney from a donor that is 48 would most likely also accept that same kidney if the only difference is that age was 49 or 50. For dichotomous characteristics, if they are yes, they must always be matched and if it is no, then it can be yes or no for the transplant program qualifying so that it is the same or worse.

Kidney matches with non-mandatory shares were looked at through the Organ Center during 2018 were looked at to analyze for the potential impact of KAP with an accelerated process in place. About 1,200 matches had donors with KDPI 80 or above and qualified to go through the accelerated placement process. Of those, 209 accepted matches that would not be changed and 41 accepted matches that may change, meaning the transplant program may not have been part of the qualified transplant programs. Most importantly is that 958 matches did not have any acceptance.

The three main project impact areas are 1) decrease placement time, 2) better organ quality, and 3) increased utilization by getting more transplant recipients, decreasing cold time/placement time, increasing use of marginal kidneys, and using resources efficiently.

There is an evaluation and monitoring plan for KAP. A Data and Safety Monitoring Council will consisting of five volunteers (one from UNOS, two from transplant centers, and two from OPOs) will evaluate and monitor to ensure KAP has the intended positive impact and consider how the evaluation metrics can be used moving forward. The pilot will be 1 year to review the impact, followed by recommended next steps to help inform policy development, make modifications to the current algorithm, or help with expansion of the pilot.

The details concept has been presented to the Kidney, OPO, Membership and Professional Standards, and Patient Affairs Committees, who were all supportive of this project. They pointed out three areas that have been addressed already. These are accounting for moving centers, as previously mentioned; consideration of Kidney Committee’s dual and en bloc kidney policy projects; and geography changes in allocation in the future. KAP will only focus on single high KDPI kidneys and there will always be a category of hard-to-place kidneys on the bottom of the match that will align with whatever changes happen with allocation.

In summary, the above feedback has been obtained; there is a transparent communication and implementation plan; key stakeholders, OPOs, and the transplant community will be kept updated on how this project will impact them; and then the Organ Center would like to begin the year-long proof of concept with ongoing evaluation through the Data and Safety Monitoring Council.

One operational concern brought up by an Executive Committee member was whether the Organ Center has thought about how this could help with getting organs from point A to point B because he recalls having to back out of offers because of long travel times. The Organ Center has been collecting data for a couple of years on how well they can move organs, although they don’t have many conclusions yet. Logistics might be referring to a follow-up project, as this project is mainly about trying to get offers out sooner.

Another comment is that using words like “non-utilization” and “hard to place” is very much appreciated, rather than more negative language like “discard” or “marginal.”

There is an offer filters project also going on. One question was whether that would intersect with this project or whether they would be completely different. The plan is to stay out of the way of other projects at implementation, similar to how they are avoiding the dual and en bloc kidney projects. They want to make sure they don't mix the data, which could happen if too many things are implemented at the same time. There will be some inherent overlap with the offer filters project in data collection, but strategies to divide out the data to understand the impact of one over the other have been discussed.

In regard to the 958 non-matches previously mentioned, would the number be twice as large for two kidneys? The 958 number is at the donor level. There was no acceptance made once the donor got to the Organ Center.

The Chair stated it sounds as though there is a general support for this project.

5. Policy Corrections and Clarifications

Occasionally when policy is developed, there is an opportunity to make language clearer.

First are updates related to administrative tasks that need to be done to be consistent with the new OPTN contract. One change is to update the Transplant Administrator Committee (TAC) official charge. TAC has had a dual role to help with educational function (primarily planning the transplant management conference) and consider issues related to the transplant community and OPTN more broadly). As a result of the new contract, TAC will be split into two groups, one to focus on the non-OPTN educational activities and the other to do the OPTN, which is to inform and create policy of interest to transplant administrators. The second change is to remove two references of "OPTN/UNOS" in OPTN policy 11. The third is a language clarification to the new liver policy in regard to the closed variance for Hawaii and Puerto Rico. The language of the variance was vague, implying to some that within Hawaii or Puerto Rico the entire match run would have been exhausted before offering organs outside, instead of just the intent of just applying to blood type O organs.

A motion was made and seconded for the Executive Committee to approve the policy corrections and clarifications as above and in the materials distributed to the Executive Committee on April 5, 2019.

A voice vote was taken and the results were as follows: 100% yes; 0% no; 0% abstained.

The second update is not a policy change, but a potential operational change in the way offers are delivered by the IT system. IT convened a group of OPO users to look at sample match runs under the new liver policy to get an idea of what those will look like and what adjustments might need to be made. One thing they pointed out is limits on the system in the way that offers are delivered apply differently if no changes are made. Currently, an OPO can make as many simultaneous offers within the DSA as it wants to, which they more often do with difficult-to-place organs. With circle-based allocation, candidates in the first unit of allocation might be outside the DSA and subject to limits on the number of offers that can go out at the same time. Some OPO users were afraid that could bog down the system; however, this doesn't change the order of candidates.

Options to consider include: 1) leaving it the way it is, although recent feedback is that this is a challenging logistical problem and OPOs need the flexibility to make more offers at one time; 2) treat the circle as first unit of distribution and apply the same rules as applied to the DSA, which is the OPO can make many offers at the same time within the first circle; and 3) potentially getting a higher limit for all parts of the allocation system at any distance, although this option would not be programmable prior to the 4/30/2019 new policy implementation. Therefore, the second option will be recommended. A workgroup on some of the logistical issues that might

need to be changed such as offer limits could be convened, leading to a long-term decision on how the offer limits should play out.

The Committee Chair asked if the IT delivery system change would apply to all the other organs down the line. It potentially could have happened with lung, but the number of centers is so low.

One Committee member said she has frequently had to wake up in the middle of the night to receive offers, so for the current need, she agrees with the proposal. In the big picture applying to all non-kidney organs, maybe geography can be taken out of it completely, and have a range of 1 to 5 for 18-year-old perfect donor who is 5'10". That way, the OPOs can tailor their needs based on the type of donor they have. Something like this would be a good discussion for the possible workgroup that would look at all the logistics. The ideal system would be to have organs accepted on the first offer, so the better the understanding of who will take the organ, the quicker it can be done, and the less time wasted by the OPO and centers receiving the calls.

Another Committee member asked when the 150 nm comes into play. For status 1's, it would be the first unit and then as getting into the MELD categories, 150 would be the first unit of allocation.

6. Geography Projects Update

1. The update includes three active proposals.
    - The first active proposal update is on the liver policy implementation. On 4/15/2019 will be an NLRB webinar will be to explain what is happening with implementation of NLRB, including the conversion criteria. There will be a town hall public forum Q&A about upcoming liver changes more broadly on April 17th and an NLRB training webinar the following day. Liver implementation is on target for 4/30/2019.
    - The next active proposal update is on removing DSA in heart allocation. The public comment wrapped up and the Thoracic Committee will meet in-person next week to discuss the final proposal to come to the Board in June and the draft briefing paper that is in process. The public comment proposal replaces DSA with a 250 nm circle (several distances were considered), to remove the language around prioritizing someone with a heart sensitization, and to make policy around thoracic consistent by removing the term "zone" and replace it with nautical miles. As the Thoracic Committee developed the proposal, there was not a clear consensus between 150 nm and 250 nm. The public comment on that was also inconclusive, but there has been conversation on whether 150 nm makes more sense.
    - The last active proposal update is removing DSA in VCA distribution. That proposal used a 750 NM mile circle. There was a fair amount of public comment around this, a lot at the regional meetings where there were centers who performed VCA transplant. Feedback concluded and Committee met and voted 13 yes, 0 no, 1 abstain to reduce the circle to 500 nm, which is what will go to the Board. There is not a lot of data on this and only one data point accepted it at more than 500 nm.
2. Next is the kidney and pancreas policy proposal development. There was a concept paper and public comment period with a large amount of public feedback. Much of the feedback was focused on the modeling, which showed decreases in transplants up to 15%. They were very valid points. A lot of work was done with the SRTR around the modeling, and different ideas were posed to the Committees in terms of how they could adjust modeling to be more realistic with what a distribution change would look like.

It is important to understand that the models they ran took into account the existing distribution, which is DSA and region, because they didn't have anything to model the circle. They looked at acceptance models, key factors, and found that "local" was a defined as DSA. If DSA goes away, then that factor is not predictive of acceptance behavior; but an arbitrary value. The circles were almost artificially restricting the estimate of who would be accepting organs. Therefore, the model run for public comment was "option 0" on the slide, which used donor characteristics, candidate characteristics, and the local designation.

They looked at other options for running the model, namely remove local or remove local and candidate and just look at donor characteristics. Five models were run for the public comment document, baseline of total number of transplants and then four geography models, which showed very little change in number of transplants. The Committees looked at these and decided to ask SRTR to remodel these in round two of modeling in preparation for the fall public comment, eliminating local and eliminating candidate characteristics. The key is being able to explain to the public that the remodeling is not about changing the numbers due to negative feedback, but about reviewing the model and figuring out what makes sense and what might provide the best representation of network behavior with the upcoming geography changes.

The KP Workgroup has been working to make recommendations to the Kidney Committee and the Pancreas Committee. Both committees worked together at the recent in-person meeting to develop a combined modeling data request to the SRTR to inform the policy upcoming policy proposal. Modeling will include all circle sizes (500, 250 and 150 nm), proximity points inside and outside the circle, all hybrid models (single circle, two concentric circles, and hybrid model) and the public comment will include all hybrid models. Models will be run with the updated acceptance model removing local and candidate characteristics, will have streamlined metrics in the proposal on how to measure whether the new policy is effective or not. For modeling, they will move up prior living donor and pediatric in the sequence behind 100% cPRA candidates.

SRTR will run 11 models. Model 1 is to rerun the baseline with prior living donor and pediatric moved up in the match priority. Models 2 through 9 are all the variations that are shown by table with various circle sizes and proximity points inside and outside the circle. Model 10 is almost like a hybrid approach inside the circle. If one is inside the circle using proximity points and has two centers, 10 and 30 miles away, from a practical standpoint that makes no difference. If using the slope concept of proximity points, there has to be a zone of indifference that the organs are close and can be driven, and the center at 30 miles shouldn't be disadvantaged to the one at 10 miles, all other things being equal. This would be a flat slope, followed by a declining slope inside the circle. This will be run out to 150 nm. Then model 11 would be the concept, but with the zone of indifference out to 250 miles for the 500 nm circle.

The SRTR modeling results will be expected early to mid June. There will be public listening sessions in the summer before public comment opens, but the Committee is still in the planning stages. Public comment period will be 8/2/2019 to 10/2/2019 with two separate kidney and pancreas policy proposals, each based on the same modeling run. Then there will be a fall public comment with the goal of having a fully-vetted policy to eliminate DSA and region in K-P distribution to the Board in December.

3. Lastly is looking beyond eliminating DSA and region to continuous distribution allocation. Many stakeholders agreed the first project for continuous distribution will be for lung. The plan is to have a concept paper ready for fall public comment, which will mainly help the

public understand what continuous distribution is. The results of that public comment will help set a timeline for actual policy changes.

The Lung Continuous Distribution Work Group has been created and has begun work on this. Continuous distribution is not just about geography, but getting relative weightings for all the different factors in allocation. The Work Group is looking at factors that might be considered in rank ordering candidates who get lung offers. A graphic was shown indicating the factors that are considered within the current lung allocation system and how those are categorized.

The Work Group is going through each factor and deciding how important the factors are, what the relative weight is, and whether there are cliffs (binary cutoff of either/or). For example, the pediatric cliff for a candidate under 12 years old is priority 1 if positive for respiratory failure and pulmonary hypertension or 2 if negative. Should priority 1 candidates always have an absolute advantage over 2 or is there a methodology to smooth it to a slope? When everything comes together, there will be a mathematical model for relative weightings of the different factors and if anything needs to change in the calculation of the factors to help smooth the cliffs put together into a single continuous distribution score. Important factors will of course be geography and distance as it relates to cold time, cost, transportation, and logistical issues.

A summary of the 1-year lung post-allocation report was then presented.

The first graph showed deaths on the waiting list per 100 patient years by Lung Allocation Score (LAS) group. The pre was the 1-year changes and the post was 1 year after. The green line of the sickest candidates with LAS 70 and above who already had a high mortality rate on the waitlist, showed a slight increase, but which was not statistically significant. The red line representing LAS 60 to 70 had a decrease of about 50%, which was a statistically significant reduction.

The second graph showed number of transplants pre and post. Overall, there were 79 more lung transplants in the post year than the pre year, but no significant changes in total transplants. There was a new program approved in the post year and there was an increase in donors, so most likely the slight increase in total transplants was not due to policy. There was some regional variation, including a new program opening up in region 9.

A third graph showed another look by LAS group of the total transplants in pre and post. There was a shift, which wasn’t the intention of the policy, that sicker people were getting more transplants. There was a significantly significant increase in transplants for the three highest LAS categories, which was part of the goal of the policy.

The last graph showed distance travelled. The average distance that lungs traveled for transplant increased from 114 nm to 166 nm pre versus post, although most lungs (77%) were still conducted within 250 nm of the donor. There have been some reports of doubling of procurement and transportation costs, but there are no data to report on that. This is a concern that will be monitored as more transplant center and OPO reports come in. Trade-offs will be evaluated in terms of whether this is an acceptable increase in cost, given some of the other benefits in terms of the sicker candidates receiving more transplants.

Utilization rate by OPTN region was evaluated. National utilization rate has not changed really at all, but when looking by region, there have been some interesting differences. More analysis still needs to be done to understand what that is and in terms of certain distances and behaviors.

In conclusion, project plans are proceeding, kidney and pancreas are on the horizon, the impacts from changes are being monitored, and this will be the beginning of the continuous distribution journey.

The Committee Chair felt that a couple of talking points around the SRTR modeling might be helpful, since there has been scrutiny and confusion around it. Being able to explain the modeling to the community will be of benefit. This will be done over the next couple of months as the next round of modeling is done.

One comment regarding pre and post 1-year lung post-allocation was that it would be interesting to compare post to what was originally projected through modeling and to see how close the modeling came to the actual post data. It was agreed this is a good point that can be evaluated.

One question was whether any of the utilization rate numbers were statistically significant and whether those numbers were compared with the amount that organs or traveling or any if any multivariate analysis was done in terms of determining why. Some of it is that the numbers are too small to do some of that analysis, so as more reports come in, more determinations can be made in how to split out the data. The last graph showed more directional outcomes, as opposed to statistically precise.

Utilization rates overall did not change, but there is another slide from the data set that stated non-utilization went up, so trying to reconcile those two things is very complicated. The Committee Chair wanted to make the Committee aware that there are people out in the community saying that the number of organs that could have been transplanted but weren't actually went up, and if looking at utilization rate, it doesn't look like that's the case. Therefore, it depends on how one looks at the numbers, as it is still too soon. She felt utilization rate is a better way to look at it, but it depends on which chart is being used, the point that is being made, and one's beliefs in trying to use the data. It's still very early and people may hear that comment, but right now it doesn't look like that has been the case.

One Committee member stated cost was big discussion at many of her regional meetings. The graph showing that organs traveled further doesn't mean it was much, much further, so perhaps they traveled by land. The question was whether there was a way to quantify whether they were driven or flown and if it resulted in a great increase in cost. The answer to that question was not available today, as qualitative data rather can quantitative are currently available. The system does not capture the method of travel very well, so costs specific to travel type are not accurate and further work needs to be done to assess actual cost. The Committee Chair stated that the organ transplantation community needs to be aware of anecdotal data around transporting organs back and forth and in the future figure out what can be done to deal with that. OPOs have all that specific information, but it is not reported in the system.

This will likely continue to come up as data comes in for all the different organ systems, so is there a plan to understand cost factor with transportation? Internally in the next week or two, assessment will be made on what it takes to gather that information in a meaningful way to really understand cost across the system. The Chair felt it will be important to get this message out to the Committees and the community.

One comment was that a recent paper in the American Journal of Transplantation that suggested that the organ cost of lungs went from $34,000 to $70,000 a lung. In addition, it may be difficult to parse out the impact of that, so if patient's length of stay were reduced and waitlist mortality was dropped, it would be impactful in different ways. If just looking at isolated costs, it might look like a huge jump in organs flying, but if a candidate's ECMO were shortened from 30

to 10 days, there has to be an offset built into the model. Analysis of this will require experts in healthcare economics.

7. Board Report Preview from the Ad Hoc Systems Performance Committee (SPC)

The SPC will be presenting at the upcoming Board meeting the work of transplant professionals (physicians and non-physicians) across multiple disciplines who were selected because they published their efforts in trying to improve donation and transplant across all organs or because they had something to contribute, as well as patients and donors, HRSA and SRTR partners, and UNOS staff.

The work began early last year, divided into three work groups: OPO, Systems Dynamics, and Transplant Program. Each Work Group was chaired by an OPO leader and a transplant leader, but there were also other influencers/external stakeholders that included CMS, HRS, SRTR, payors, legislature, patients, donors, families, and many others. The hope is to be able to continuously engage the other influencers to demonstrate the sincere efforts of the Committee.

SPC's charge was strategic, community-driven, interdisciplinary, measurable, transplant conversation to determine how to best improve performance, what tools can be used to foster collaboration, and what could be recommended for next steps for new or existing tools and strategies. Members were given the blue sky scenario, to discuss what makes a good OPO and good transplant program.

The SPC was made up of 60 members who were broken into the three Work Groups. There were three in-person meetings, 39 Work Group conference calls, around 115 ideas were generated and documented, consisting of over 2,100 staff hours by 25 dedicated staff members.

The final meeting was an in-person meeting held in Chicago attended by 110 Committee members, staff, and government attendees. The work was mostly done through breakout sessions organized by key theme. The sessions sought to gather discrete input aiming for consensus and to prioritize where possible, which was done both within the separate Work Groups and with the group as a whole. UNOS also provided feedback cards after the sessions to provide additional opportunity to participation.

Early themes members came up with related to 1) data transparency and data sharing key to benchmarking for self-improvement of transplant centers and OPOs, 2) increasing collaboration, relationships, and standardization of practices that will support broader sharing, and 3) performance is reliant on members being good stewards in their own actions.

Recommendations that came from the work were as follows.

1. New research tools and technologies.

   There was discussion around a dashboard, self-monitoring metrics and the opportunity to benchmark within DSA and region, research IT tools looking at predictive analytics, organ recovery, including timing and transparency of offers, and transportation, including making ground and flight arrangements.

2. MPSC performance monitoring/measuring enhancements.

   There was much discussion around OPO balanced scorecard, including a reportable denominator that can be agreed upon, and what can be done to minimize the angst with self reporting. Around the transplant balance scorecard side there was discussion around possible composite metrics for improvement. There was also discussion around the audience for this data, which could be both internal and public.

3. Opportunities to look for beyond OPTN.

OPTN and UNOS could serve as a convener of all the other influencers outside of transplant professionals as mentioned above. There was discussion about what could be done around transportation; payment models and financial paradigm; opportunities for societies to advocate together for policy making where applicable and to partner with UNOS lobbyists to do the same; expand private side of OPTN scope, recognizing the desire to have recommendations to all external stakeholders.

4. Collaborative improvement and relationship management.

   There was much discussion around looking at more COIIN-like projects and which of those could continue to drive collaboration through relationship building across OPOs and transplant centers. One discussion was around perhaps revising the format of the current OPTN and UNOS regional meetings, recognizing that the new region will be defined by nautical miles instead of state geography. Also discussed was enhancing and managing relationships at the local level.

The Committee's work will ultimately result in key actionable recommendations, identifying performance measures for driving system performance, and prioritizing the actions and whether there are any immediate changes or projects that can be done.

The following are examples of some things that were discussed at the in-person meeting.

When looking at the dashboard for internal validation and overall performance monitoring, there were hundreds of metrics within and elements, but these are a few that rose to the top. On the OPO side, the Committee came up with things like transplant yield and authorization failures. OPOs probably do this well already, but the idea is to share them more with one another so that everyone benefits. On the transplant program side, things like late turn-downs and declines and the time it takes to decide whether or not to use an offer were troublesome to a lot of programs, as that led to organ discard. When looking at acceptance of hard-to-place, DCD, and PHS high-risk organs, and a centralized recovery, are programs going to be accepting the opportunity to have other programs retrieve organs to avoid the necessary work to transport organs.

When looking at collaborative improvement projects, it was recognized that the COIIN project was a success in getting people to look at their data, communicating with one another more effectively, and sharing best practices. Many ideas for future collaborative improvement projects were discussed, but a few of the ones that were brought up the most included transportation efficiencies, effective DCD procurement practices, DCD utilization, OPO standardization and strategies for procurement, and increasing living donation.

Much of the time was spent on recommendations for top potential predictive analytics. If transplant programs were given data to help them make decisions, what would that data be? Several examples were shown in a graphic. Both OPOs and transplant programs wanted real-time data that would be updated on a regular basis, such as an organ offer or being able to educate a patient about a particular organ offer. It was recognized that there is ample opportunity to begin to see which ideas are available now and which will require more work.

A work in progress is the balance scorecard, which will hopefully be more concrete by the June Board meeting.

Next steps will be to deliver the full report of key themes/takeaways and recommendations for projects/strategic actions to the OPTN Board in June. There will also be opportunity to share this conversation with the broader community. There are confirmed presentations at the Transplant Management Forum, American Transplant Congress, Donate Life America, and Association of Organ Procurement Organizations meeting. The hope is to be able to publish the

work in the future, and continued execution of this work through committees or smaller work groups. The SPC recognized and thanked UNOS research staff for their work on this initiative.

Executive Committee members had no specific questions on this project. The Committee Chair thanked the SPC for their time and efforts.

8. Policy Oversight Committee (POC) Update

A summary of the new OPTN projects evaluated by the POC and which the POC recommend for approval by the Executive Committee was presented. There were three project proposals.

1. Thoracic Committee - Policy development of continuous distribution of lungs, which will fall under the strategic alignment goal of providing equity in access to transplants. There was broad agreement from the POC that this needs to be an organization priority. There were some questions about the timeline being aggressive, but urgency was felt since it is an organization priority. The timeline is a concept paper in the fall with policy proposal next spring. POC supported this proposal as phase two of the Geography Committee's work in eliminating DSA and region already underway.
2. Living Donor Committee - Guidance for transplant hospitals on transplant candidate use of social media to find living donors, which will fall under the goal of increasing number of transplants. This guidance has been requested in the past, which led to this proposal. POC agreed this is a topic worthy of some guidance, though there was one question about whether it is in the scope of the OPTN. The response was that the project will provide some uniform guidance, as opposed to a policy proposal. Rather, it will consist of expectations to provide consistency on the safe and effective use of social media campaigns. The project will not be resource-intensive.
3. Histocompatibility Committee - Modify the appointment process for the Histocompatibility Committee Vice Chair, which falls under the goal of promoting efficacy in donation and transplantation. The process for appointing the Histocompatibility Vice Chair has been out of sync with the rest of the committees for quite some time. The reasons it was set up differently originally have not proven to be of concern to the Histocompatibility Committee. The POC agreed it would be important at this point to have a consistent approach.

The Committee Chair commented that social media campaigns make people a little bit nervous, so it is good that there will be some guidance there for it. Another comment was that at a recent in-person meeting, the Ethics Committee expressed interest in this project as well. It might be an opportunity for creation of a combined work group from the Ethics and Living Donor Committees.

A motion was made and seconded for the Executive Committee to approve the establishment of the three new OPTN projects just described above.

A voice vote was taken and the results were as follows: 100% yes; 0% no; 0% abstained.

9. OPTN Budget Preview

The Finance Department reviewed the budget for fiscal year 2020. They began the base year of the OPTN contract in April 2019, which will run through 9/30/2019. The budget year in review will begin 10/1/2019.

Some items within the new OPTN contract that have a cost and will be part of the budget include looking to review and analyze the OPTN regional process; continuing to develop innovative applications to enhance the match function; collecting all OPTN data through electronic transfer to the APIs that the IT group is working on; looking to develop new models for

member improvement with a focus on branding of OPTN materials to have a more clear distinction between OPTN and UNOS; Network Operations Oversight Committee, which will be involved in looking at IT work and submitting; and also submitting clearance packages for OMB approval.

The majority (about 90%) of funding for OPTN network comes from the registration fees. Registration has increased tremendously each year since 2015. Current year registration is predicted at 60,000, which will be an all-time high, resulting in a tremendous increase in funding available through OPTN.

The budget overview shows a $3.3 million increase over the 2019 budget. The main reason for this is new work within the contract. Since the funding was strong, they asked leaders during budget meetings if OPTN can allocate more resources, what can they provide. This allowed the addition of a few bodies to the 2020 budget to get some of these things accomplished.

Salary vacancy was reduced and the hope is to build new teams in those areas in the future. Salary and benefits increased about 1.5 million with the addition of about 11 full-time employees related to new contract activity. The new positions included one new administrator, three positions for the Policy and Community Relations group, one for the Meeting Partners group, one for the Communications group, and four new software engineers for the IT group.

Travel costs for the year increased about $100,000 from the prior year, as one of the key goals is to analyze the regional process for getting information out to all the different stakeholders nationally. There will also be collaborative improvement travel and the learning congress to continue the work of COIIN in the prior year. Other costs are increased consulting to accelerate IT projects, increased hardware and software maintenance, and added tools for data governance and ICD-10 requirement within the new contract.

Indirect costs change as the total direct costs of the contract change, which were estimated at about 12.5% based on the most indirect cost rate proposal for fiscal year 2018.

The majority of funding goes to electronic matching of organs (40%), followed by data services (14%) and compliance and performance (13%), OPTN governance (19%), and then some smaller amounts for policy development, security and privacy, and communications.

When talking about strategies for setting OPTN fees for the year, there has been a growth in the OPTN cash balances. There has been significant growth in the past 5 years in those balances to the point where OPTN reserve reached its 3-month funding goal, so no further registration fee money will go into the OPTN reserves. That will be allowed to continue to grow with a plan for that in the future if there is continued growth in that area. However, there is a concern about increases in operating balances. Ideally, the OPTN operating and reserve balances should remain about equal, but what was seen was a few years of registrations that came in over-budget and expenses that came in under-budget. Therefore, an effort will be made to spend-down the OPTN cash balance throughout the remainder of the contract through 2023. The Finance Committee and the Board set a 2-month to hold within the operating account of about $9.1 million based on the proposed 2020 budget and a little less than $15 million of excess funds for the operating account.

Looking at the total OPTN expenses, there is HRSA funding ($5.5 million), which will increase by half a million per year of the contract up to $6.5 million in the final 2 years. There will be a $2.5 million spend-down which allows for a $46 reduction in OPTN fee to $748. Assuming addition of bodies for additional work throughout the contract, each year going forward looks to be a 4% to 4.5% increase in total cost with some flexibility with excess funds and the operating account.

In conclusion, the finance team considered the budget carefully and felt it was important to get the word out to the community that even with increased costs, the total registration fee would be reduced.

Executive Committee members had no specific questions on budget. The Chair thanked the Finance Department for their work.

10. OPTN IT Update

Work is still on target for the liver implementation release date set for 4/30/2019. Liver will be a little different than other organs because the NLRB and liver distribution will be implanted at the same time. The approach is to develop liver distribution by software engineering so implantation will not be just in terms of implementing correctly, but what happens when the new policy is deployed and preparing for any complexities that arise.

The community is being prepared for the release differently this time around. IT created a method of testing because OPOs have ability to make offers at the same time. All 58 OPOs will have the ability to access on the user acceptance environment to understand how it works. In addition, NLRB users will be able to navigate the exception forms to become familiar with any differences with the new policy.

IT created something called Testify. They gathered many stakeholders from policy departments, research, and member quality, those who use UNET. They had them go through the workload and incentivized them to look for any mistakes issues or any questions that might come up. For example, the Hawaii/Puerto Rico issue discovered during this exercise. As a result, IT made some additional changes and will be ready for the end of the month.

Over the past 4-1/2 years, the transplant community has been talking about truly transforming all sides of the way they work. Why is this important? Because it is important improve how data flows, how many mistakes people make, get people out of data management, let systems talk to each other, and automate make submissions through UNET.

The idea is to build information bridges or Application Program Interfaces (APIs) to make submission of information through UNET or extraction of information from UNET more standard, more automated, and requiring less manual data entry. The approach to reaching this goal is a multi-year journey.

One focus will be to start on those areas as a new extended program is being developed to try to introduce more automated ways to submit information in areas where there is no way to automatically submit data today. Waitlist is one example where all the data entered is manual. Automation will eliminate duplication of effort and create improvement of opportunity for data accuracy.

Another focus will be to go away from old methods used 15 years ago by institutions to interact with UNOS, and instead to embrace how the rest of the healthcare industry embraces technology, which is API.

IT will create a plan to eliminate current ways of submitting data through files and import/export methods. For example if an OPO needs to register a donor or list an organ, when they enter it into their system, once the information is complete it will flow into UNET automatically. This will improve the focus on clinical care, rather than on administrative tasks. IT realized they have to get better at explaining to the transplant community why this is meaningful and how it will help focus on implementation of policies faster.

Lastly, there will be less of a focus on time-consuming maintaining of old methods and more focus of the software engineers on implementing policies and changing UNET itself to be more "Lego-block-like."

A metric-driven approach will be used to get the work done. The first step is deliberate gathering of statistical data about how information is submitted today. For example, very few transplant centers actually use Tiedi forms, so IT will figure out what make those forms so unpopular. The data gathered will be used to create new APIs and new methods of submitting information.

In conclusion, the work will take anywhere from 6 months to 2 to 3 years, and will require communication and collaboration with vendors (EHRs) and members using other technologies. The goal is that in 2-3 years there will be no methods of submitting information electronically to UNET outside of APIs, and an automated way for information way to flow from and to UNET.

The Chair recognized the work of the IT Department. Executive Committee members had no specific questions on the IT update.

11. Adjourn

The meeting was adjourned.

Upcoming Meetings

- June 9-10, 2019, Richmond, VA (to include new member orientation)
- December 2-3, 2019, Dallas, TX
- June 7-8, 2020, Richmond, VA