**OPTN Policy Oversight Committee**
**Meeting Summary**
**October 14, 2020**
**Conference Call**

**Alexandra Glazier, JD, Chair**
**Nicole Turgeon, MD, Vice Chair**

**Introduction**

The Policy Oversight Committee (POC) met via Citrix GoTo teleconference on 10/14/2020 to discuss the following agenda items:

1. Workgroup Recommendations: Provisional Yes
2. Evaluation of Efficient Matching Workgroup Recommendations
3. Multi-Organ Policy Review Workgroup Update
4. Kidney Pediatric Project Update
5. New Projects

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

**1. Workgroup Recommendations: Provisional Yes**

The Chair of the Provisional Yes Workgroup (PY Chair) presented the workgroup's recommendations. The POC heard the recommendations from the other two efficient matching workgroups – Local Recovery and Biopsy Standards and Practices – during their meeting on 9/9/2020.

Summary of discussion:

*Provisional Yes Workgroup Recommendations:*

- Develop a dynamic match run
  - Timeframe: 12-18 months
  - Priority: High
  - Proposed sponsor: Operations and Safety Committee (OSC)
- Create additional acceptance codes to indicate conditional yes
  - Timeframe: 6-12 months
  - Priority: High
  - Proposed sponsor: Organ Procurement Organizations (OPO) Committee
- Increase offer filters
  - Timeframe: 12 months
  - Priority: High
  - Proposed sponsor: UNOS IT

*Discussion*

The PY Chair explained that the dynamic match run idea was borne out of observations from transplant program staff that they receive offers before there is a lot of information available on the organs. A dynamic match run would screen programs off the match run based on their acceptance criteria as more information becomes available. A member recommended including human leukocyte antigen (HLA) data as information that would be updated in a dynamic match run.

The Chair asked how conditional yes would work in conjunction with the dynamic match run, and whether this would create additional work for OPOs to review conditions one at a time. The PY Chair explained that the program receiving the offer would be able to enter additional information in a free text box regarding their conditions for accepting the organ. It would be more work for the OPOs, but it might take less time than it would to make an additional phone call when fighting the clock post-procurement. A member said the conditions could be automated for some information, like lab values.

The PY Chair said that each of these recommendations could stand on their own, but they are complementary and would each be more effective if implemented together. A member asked if UNOS IT had been consulted on these recommendations since they could be costly and time-consuming. The PY Chair affirmed that UNOS IT was involved with the workgroup. While the recommendations have substantial programming demands, they are doable with some time.

A member asked how the recommendation to increase offer filters relates to the existing pilot project. The PY Chair explained that the pilot project has received positive reviews, but the offer filters in the pilot are not set by default. The Workgroup recommends that UNOS apply default filters based on a program's historical acceptance practices, and expand offer filters to more programs.

A member asked if the offer filters would be aligned with conditional acceptance, since there could be some efficiencies by aligning these tools and it would make them easier to understand. The Chair said the dynamic match run and conditional yes also overlap since they both relate to changing factors in the donor. UNOS staff said that UNOS has been monitoring where there might be efficiencies to do this work at the same time to maximize the benefits.

A member said he has observed larger volumes of organ offers for heart and lung, including one case where the OPO offered an organ to 500 programs within an hour at the beginning of the match run. The member said that offering organs to 100 programs seems to be common, and for a marginal organ, it takes a long time to go through those offers. Transplant programs get so many calls that they enter provisional yes because there is not time to diligently review each case. The member asked if the workgroup addressed these concerns. The PY Chair said the workgroup discussed these issues and came to the conclusion that the system has certain behavioral incentives for both OPOs and transplant programs to look out for their own interest in ways that make the system less efficient. The workgroup's goal was to eliminate some of the incentives in the system for behavior that reduces efficiency. The Chair said that the workgroup also considered a recommendation on limiting the number of offers but decided not to move it forward as it may have unintended consequences.

**2. Evaluation of Efficient Matching Workgroup Recommendations**

The POC evaluated the recommendations from the three efficient matching workgroups to assess which ideas would have the biggest impact on increasing the number of transplants and promoting the efficiency of the OPTN. The POC also reviewed the estimated timelines for the proposed projects and the recommended sponsoring and collaborating committees.

Summary of discussion:

*High Priority Recommendations that Involve Policy or Guidance Changes*

- **Provisional Yes:** Create additional acceptance codes to indicate conditional yes
- **Local Recovery:** Consider expanding expedited placement policy to all organs
- **Biopsy:** Develop a minimum set of donor kidney criteria appropriate for biopsy
- **Biopsy:** Develop guidance to maximize the use of image sharing technology

### *High Priority Recommendations Involving System Changes*

- **Provisional Yes:** Develop a dynamic match run
- **Provisional Yes:** Increase offer filters
- **Local Recovery:** Streamline communications in DonorNet®
- **Biopsy:** Develop a standard form that pathologists would complete during biopsy readings

### *Recommendations Identified as Medium or Low Priority*

- **Local Recovery:** Develop guidance on consistent practices for the organ recovery process
- **Biopsy:** Develop a minimum set of donor criteria appropriate for bedside liver biopsy

### *Discussion*

#### Biopsy Standards and Practices

The Vice Chair of the Kidney Committee (Kidney VC) said that a standard pathology report for kidney may not increase efficiency or transplants, and may increase discards. The Kidney VC outlined three problems with making a decision based on a kidney biopsy: (1) frozen specimens do not yield the best information; (2) small hospitals may not have a nephrologist, so the quality of the report may not be very sophisticated; and (3) there are a lot of variables, including the location of the specimen, that reduce the value of conducting a biopsy on a kidney. The Vice Chair explained that the project would include identifying what criteria should be included on a standard report, like whether the specimen is frozen. The intent is not that the report would be used as a decision-making tool, but that a standard report would eliminate some of the variability. The Kidney VC said that standardizing the information reported for kidney biopsies would be useful. The Vice Chair of the Disease Transmission Advisory Committee (DTAC) said that DTAC would be interested in collaborating on this effort.

Members expressed support for developing guidance on when it is appropriate to conduct a biopsy, since data suggest that biopsies are often used as a reason to turn down a kidney. A member said that for liver transplant, having an image of the biopsy is often more helpful than a report, in case the hepatologist does not have a lot of experience with liver biopsy. The member said that having the ability to review biopsies in DonorNet would expedite allocation.

#### Local Recovery

A member recommended involving the Lung and Heart Committees in projects related to local recovery since local recovery can be controversial for thoracic organs, particularly lung, depending on the local recovery center and their experience. The Chair agreed with the suggestion, noting that there is no recommendation to require local recovery.

A member said that while guidance on consistent practices in organ recovery was identified as a lower priority, the issue is pressing due to broader sharing and different wait times. At the member's program, five organs were lost in local recovery in their last six kidney-pancreas transplants. There is a wide variety of experience among recovery surgeons; it varies whether or not the OPO pays the recovery surgeon; and there have been circumstances where the surgeon refused to do local recovery. The Chair said that the workgroups saw value in all of their recommendations but the POC must decide which recommendations will have the most value in terms of resources and impact.

The Chair suggested waiting until the community has more experience with broader distribution before pursuing guidance or system changes related to local recovery. A member agreed that local recovery is complicated and it could take a long time to develop policy, whereas the other work seems more straightforward. The Vice Chair from the Ethics Committee said that if the local recovery work moves forward, the Ethics Committee would like more information on how to support that work. The Chair

explained that once the prioritized work is assigned to committees, those committees will identify collaborators.

A member said it might not be appropriate to prioritize local recovery at this time, but the issue should not be brushed aside because it is complicated. The member suggested that UNOS consider a separate workgroup to consider how to address this issue at a national level in the long run. Transplant is a mature field but staff are still flying all over the country to get organs. The UNOS CEO agreed and said UNOS and professional societies will be discussing the COVID experience and what worked well. There is a conversation to be had, and UNOS and the OPTN will host some of that conversation, which could inform whether policy is needed in the next few years. There is a best practices approach to seek first before advancing to a policy stage.

The Chair noted that one of the system recommendations to improve local recovery was communication enhancements in DonorNet to facilitate information sharing. The Chair asked if this work should move forward in the more immediate future. Members agreed that this work could move forward, since it also ties into some of the other system improvements like image sharing.

### Provisional Yes

Members said that the provisional yes recommendations would make the system more efficient and that addressing provisional yes is the highest priority. The Chair noted that all three provisional yes recommendations are related: conditional yes, dynamic match run, and offer filters.

### POC Recommendations

The POC reviewed the recommendations by proposed sponsor alongside the committees' current work.

- **OSC**: The POC recommended that OSC move forward with projects focused on communication enhancements in DonorNet and image sharing for biopsies. The Chair noted that when the POC reviews a new project from OSC later in the meeting, the POC will need to consider the committee's time and resources and whether the POC needs to prioritize that work.
- **OPO Committee**: The POC recommended that the OPO Committee move forward with the conditional yes project, and hold off on the local recovery project on expedited placement.
- **Kidney Committee**: The POC recommended that the Kidney Committee move forward with the project to develop a minimum set of donor kidney criteria appropriate for biopsy. The Vice Chair said that this project would go hand-in-hand with the effort to develop a standard pathology report, and these projects probably will not take a lot of time.
- **Liver & Intestine Committee**: The POC recommended that the Liver & Intestine Committee move forward with the project to develop criteria for bedside liver biopsy. While the committee has several ongoing projects, this project is not large or long-term.

Next steps:

The POC recommended prioritizing the provisional yes projects and the biopsy projects, and holding off on the local recovery projects except for communication enhancements in DonorNet, which will run concurrently with the image sharing project. POC leadership and UNOS staff will develop a sequencing plan to share with the committees by the end of the month. UNOS staff will set up calls with the workgroup chairs and leadership of the committees sponsoring the work to coordinate the hand-off.

**3. Multi-Organ Policy Review Workgroup Update**

The Chair of the Multi-Organ Policy Review Workgroup (MOT Chair) provided an update on the project.

Summary of discussion:

The goal of the workgroup is to clarify OPTN *Policy 5.10.C Other Multi-Organ Combinations* to provide clear rules for OPOs. The workgroup is developing clear sharing thresholds using distance and criteria with a 500 nautical mile (nm) sharing distance. Higher status heart and lung MOT candidates would be offered a second organ, and there would be protection for higher status liver-alone and kidney-alone candidates. OPOs would still follow the match run. This project will not change the order of the match run or increase priorities for MOT candidates; establish eligibility criteria or safety nets; or address current kidney-pancreas, simultaneous liver-kidney, heart-lung, or liver-intestine policies.

The workgroup sought feedback from the Heart, Lung, and Liver & Intestine Committees and Kidney Committee leadership. The OPO Committee will vote on the final policy language in November to release a proposal for the January-March 2021 public comment period, with the goal of sending the proposal to the OPTN Board in June 2021.

The Vice Chair said this is a great first step for multi-organ policy, but that it was ultimately the intent of the project – as recommended by the OPTN Board – to address the items that the Workgroup is not considering, including establishing a match run order; eligibility criteria for the different organ combinations like heart-kidney and lung-kidney, similar to criteria for liver-kidney; and safety nets for those organ combinations. Most importantly, the project should address all the different organ combinations at once and who gets first priority and why, for example, if certain single-organ candidates like highly sensitized kidney candidates should be prioritized ahead of MOT candidates. The Vice Chair asked if the project will continue after this initial proposal.

The MOT Chair said that the workgroup has identified some criteria for heart and lung, and figuring out how to prioritize different MOT combinations is something that could develop in the future. The MOT Chair said it has taken a lot of input to get to current stage of the project. The workgroup is considering whether a kidney should go to a highly sensitized candidate rather than an MOT candidate.

The Vice Chair acknowledged that this was always going to be difficult project but the hope was that the project would follow a stepwise approach to work through these challenging issues. The Chair said that a second phase of this project could be led by a different committee, but multi-organ allocation was designated as a strategic policy priority rather than just a policy project because the OPTN needs to tackle these difficult issues.

The Kidney VC said that the simultaneous liver kidney (SLK) work went hand-in-hand with establishing eligibility criteria and a safety net, so that same process could be revisited for other organ combinations. The Chair asked if this is something the Kidney Committee could take on or if a new workgroup should be established, since the OPO Committee will be assigned projects from the efficient matching workgroups. The Kidney VC said it makes sense for the same workgroup to carry the work forward since they have already reviewed a lot of data. A member asked if it makes sense to proceed based on which multi-organ combinations are most common, or whether it makes more sense to take a broad-based approach. The Vice Chair said that a combined Liver-Kidney workgroup developed the SLK policy and it was very effective and went very quickly. The Vice Chair said it may make sense to have several small workgroups but one committee should be coordinating all of the work, and the initial thought was that the OPO Committee was the most appropriate committee to oversee the work. Other organ committees could be working to develop their criteria and safety net following the blueprint established by the liver-kidney project. There are lots of ways to approach the work but the OPTN needs to develop the list of who goes first, when, and why. Otherwise, the OPTN is not achieving the intent of this policy priority. The MOT Chair said the workgroup could continue work on eligibility criteria and safety nets, but it will take more time and will involve the other organ committees.

The Chair suggested sequencing the second phase of the MOT work after some of the efficient matching work has been completed. A member said that the work that has been done to date is straightforward and addresses patients who have been orphaned by current policy, so it makes sense to finish that work and consider picking up the other issues at a later time.

Next steps:

The Chair suggested revisiting this discussion during the POC meeting on 11/5/2020 to determine the plan moving forward to address the second phase of the MOT work.

**4. Kidney Pediatric Project Update**

The Kidney VC presented an update on the Kidney Pediatric Project.

Summary of discussion

The Kidney Pediatric Project was previously approved by POC but delayed when the Kidney Committee was directed to focus on geography work. The committee recommenced work on this project in June 2020. The purpose of the project is to increase pediatric prioritization in sequence C (donor organs with a Kidney Donor Profile Index, or KDPI, of 35-85%), which currently awards no pediatric priority. The proposal is to create a new sequence for pediatric donors greater than 18 kg with a KDPI of 35-85% that previously would have been classified as sequence C. The proposal would maintain the current pediatric priority for sequences A and B and increase priority among the current pediatric donors of sequence C to mirror sequence B. The proposal is estimated to require 4,000 IT hours to implement. The committee plans to release the proposal for public comment in January 2021; send the proposal to the OPTN Board in June 2021; and aim for implementation by June 2022. The Kidney Committee discussed whether this effort should be rolled into continuous distribution, but since this has been an issue for the pediatric community and the project was already delayed once, the committee felt it was important to move forward at this time.

This project aligns with the strategic plan goal to increase equity in access to transplants, which is over-resourced. This project does not directly align with the strategic policy priorities but is groundwork for the continuous distribution project. The POC reviewed the other projects on which the Kidney Committee is sponsoring and collaborating.

The Chair expressed concern about whether this is a good use of the Kidney Committee's time while continuous distribution is ongoing, especially since this project would be a relatively large IT lift for a small number of patients, and the OPTN is over-allocated on this strategic goal. While the Kidney Committee previously had to put this work on pause for other reasons, that may not be a strong enough rationale to resume the work now.

The Vice Chair said this project is really valuable and important, but the problem is that this work was intended to update the Kidney Allocation System (KAS). The geography project added pediatric prioritization in KAS but did not cover this aspect. Since the committee has been directed to move toward continuous distribution, it does not make sense to do this project as a separate effort. It no longer makes sense to develop a new sequence since the entire system would change a year after it was implemented. That does not mean this work is not a priority; it just does not seem like the right time to make this change when the committee is already working on continuous distribution. The Vice Chair said the purpose of asking the POC to re-evaluate this timeline is for the POC to fulfill its role as a steward of OPTN resources. A member mentioned that the changes being implemented in December 2020 will also increase pediatric prioritization for kidney and will narrow the current gap.

A member acknowledged the need to reconsider the project's priority, but said there are two key elements to this discussion: (1) it is known that KDPI is inappropriate for pediatric donors, so that issue needs to be addressed in continuous distribution and future models; (2) while the Chair mentioned that maybe this work should not be prioritized in part because the numbers are small, the OPTN and UNOS should recognize that pediatrics will always be a small population. Pediatrics are a vulnerable population and committee members need to be the voice for those children, so the size of the population should not justify lowering the priority for the project. The OPTN should reconsider the concept of small impact, because in terms of equity and utility, there are clear ethical principles and practice guidelines that children should be prioritized in allocation. It is a utility issue as well because they have more longevity, as established in an OPTN white paper. The Chair agreed and explained that she meant that it is a small segment of impact for a small period of time before the shift to continuous distribution, not that having impact on the pediatric population – which is likely to always be a smaller group – is somehow less valuable or less important. The Chair explained that it was more a comment about the value of doing this project now knowing that the continuous distribution project is coming in short order.

The Kidney VC said that the timeline for continuous distribution has a lot of caveats and it may take longer to develop the proposal. The Kidney VC asked it if would it change the concerns about the resource allocation if the Kidney Committee had a different timeline for continuous distribution. The Vice Chair of the Pediatrics Committee (Pediatrics VC) said that the Kidney Committee has already been waiting three years to work on this issue, and adding continuous distribution on top extends the timeline further. During this time, all those kids are not getting that advantage that the committee thinks they deserve. The Vice Chair reiterated that pediatric candidates received more priority in the last round of allocation changes; that the OPTN is continuously striving to improve pediatric priority; and that there was some agreement on waiting for continuous distribution. The Vice Chair said this should motivate the Kidney Committee to move the continuous distribution work forward to get the desired changes for pediatric candidates in place.

The Kidney VC said that the two workgroups can be combined to focus on continuous distribution. The Chair recommended that the Kidney Committee follow that approach. The Pediatrics VC recommended identifying a specific timeline for the Kidney Committee to consider the pediatric component of this work so that it does not get lost if the continuous distribution timeline gets extended. The Chair asked the Kidney VC to identify an appropriate timeline to ensure this work is not lost.

**5. New Projects**

The POC considered two new projects: *Modifications and Education in Organ Packaging Policies,* sponsored by the Operations and Safety Committee, and *Required Reporting of Donor HLA Typing Changes*, sponsored by the Histocompatibility Committee.

Summary of discussion:

### *Modifications and Education in Organ Packaging Policies*

The purpose of this project is to standardize and identify efficiencies in organ packaging processes in light of patient safety reports of kidneys that were partially or fully frozen upon arrival. A workgroup comprised of OPO and organ preservation subject matter experts propose the following solutions:

- Data collection via the organ disposition form to further evaluate the issue
- Policy modifications to standardize packaging processes, particularly packaging materials (e.g. saline, ice placement)
- Guidance on best practices for organ packaging

This project would align with the strategic goals of increasing the number of transplants and promoting the efficiency of the OPTN, and the efficient matching strategic policy priority. The POC considered the impact of this project relative to the committee's ongoing projects; the work from the efficient matching workgroups that may be assigned to OSC; and collaborating committees for this project.

### Discussion

The Chair noted that OSC will likely have a fair amount of work based on the efficient matching workgroup recommendations, including the projects on communication enhancements in DonorNet and image sharing. A member asked what materials are supposed to be used in packaging and it if is not supposed to be saline. The Vice Chair of OSC (OSC VC) explained that sometimes saline is used, but when a solute is put in a fluid, it changes the freezing point and yields a colder solution. There can also be variation in where the sterile barrier is and whether three or four bags are used, and these variations can have a direct impact on the loss of these organs. The Chair pointed out that this issue has only been reported eight times since 2013. The Vice Chair said that the problem is more common but the damage is often minor, and the eight reports represent organs that were not transplanted. The OSC VC noted that the data are reported voluntarily so the eight cases represent just a sample of what is happening.

The Chair asked the POC to consider if this work should be sequenced following the efficient matching work. UNOS staff said there are a few other pathways for accomplishing this work since OSC has a lot of work lined up. The project could be addressed by a non-OPTN entity or referred to the UNOS collaborative improvement team. The collaborative improvement team approach could be explored further prior to an official project approval. This team could presumably bring together several experts in operations and OPOs to develop some guidance on packaging.

The Chair suggested that the collaborative improvement team take the first steps on this project by identifying best practices while OSC begins the efficient matching work. OSC could determine later if the work should continue as a policy project. The POC agreed with this approach.

### *Required Reporting of Donor HLA Typing Changes*

The purpose of this project is to require notification to OPOs and transplant hospitals when there is a change in donor human leukocyte antigen (HLA) typing, either prior to or after transplant. This notification would be programmed in UNet$^{SM}$. The POC considered the impact of this project relative to the strategic plan, the strategic policy priorities, the committee's ongoing projects, and collaborating committees for this project.

### Discussion

Members did not have any questions or concerns. The Committee voted to move this project forward to the Executive Committee for approval (19 – yes, 0 – no, 0 – abstain).

Next steps:

*Modifications and Education in Organ Packaging Policies* will be referred to the UNOS collaborative improvement team for further work. *Required Reporting of Donor HLA Typing Changes* will be considered for approval by the Executive Committee on 10/20/2020.

**Upcoming Meetings**

- November 5, 2020
- December 9, 2020

**Attendance**

- **Committee Members**
  - Alexandra Glazier, Committee Chair
  - Nicole Turgeon, Committee Vice Chair
  - Sandra Amaral
  - Marie Budev
  - Rocky Daly
  - Lara Danziger-Isakov
  - Alden Doyle
  - Garrett Erdle
  - Andrew Flescher
  - Rachel Forbes
  - Heung Bae Kim
  - John Lunz
  - Paulo Martins
  - Stacy McKean
  - Sumit Mohan
  - Martha Pavlakis
  - Emily Perito
  - Kim Rallis, visiting Board member
  - Kurt Shutterly
  - Susan Zylicz
- **HRSA Representatives**
  - Marilyn Levi
  - Shannon Taitt
- **SRTR Staff**
  - Jon Snyder
- **UNOS Staff**
  - Brian Shepard, UNOS CEO
  - James Alcorn
  - Kristine Althaus
  - Sally Aungier
  - Nicole Benjamin
  - Rebecca Brookman
  - Matt Cafarella
  - Laura Cartwright
  - Julia Chipko
  - Craig Connors
  - Shannon Edwards
  - Betsy Gans
  - Chelsea Haynes
  - Robert Hunter
  - Courtney Jett
  - Sarah Konigsburg
  - Lindsay Larkin
  - Lauren Mauk
  - Maureen McBride

    - Meghan McDermott
    - Lauren Motley
    - Elizabeth Miller
    - Kelley Poff
    - Matt Prentice
    - Tina Rhoades
    - Sharon Shepherd
    - Leah Slife
    - Pete Sokol
    - Susie Sprinson
    - Kiana Stewart
    - Kaitlin Swanner
    - Susan Tlusty
    - Kim Uccellini
    - Ross Walton
    - Sara Rose Wells
    - Joann White
- **Other Attendees**
    - Luis Mayen
    - Craig Van De Walker