OPTN Organ Procurement Organization (OPO) Committee
Meeting Summary
March 31, 2021
Conference Call

Diane Brockmeier, RN, BSN, MHA, Committee Chair
Kurt Shutterly, RN, CPTC, Vice-Chair

Introduction

The Organ Procurement Organization (OPO) Committee (the Committee) met via Citrix GoToMeeting teleconference on 03/31/2021 to discuss the following agenda items:

1. Disease Transmission Advisory Committee Request for Feedback
2. Public Comment Review: Clarify Multi-Organ Allocation Policy
3. Public Comment Review: Modify the Deceased Donor Registration (DDR) Form

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

1. Disease Transmission Advisory Committee Request for Feedback

The Chair of the Disease Transmission Advisory Committee (DTAC) presented a request for feedback on lower respiratory COVID-19 testing, impact on donor after circulatory death (DCD) lung utilization, and lung recipient safety concerns in regards to COVID-19.

Data summary:

The Centers for Disease Control and Prevention presented aggregate data on 40 reports of potential COVID-19 transmissions, 3 of which were proven or probable lung transplant transmissions.

- These cases had negative upper respiratory COVID-19 testing, and retrospective positive lower respiratory tract testing
- Highlighted risk for lung recipients if lung donors only receive upper respiratory COVID-19 testing
    - OPTN data showed only 30% of lung donors received lower respiratory testing

Feedback from OPO Committee members showed reduced barriers in access to lower respiratory testing, but concern about timeliness of access and DCD lung utilization

- Donor hospitals may not be able to cooperate with lower respiratory testing requirements
- Lung programs may not accept lungs with pending lower respiratory test results

There is sufficient concern for patient safety in potential disease transmission to lung recipients for DTAC support of emergency policy change, but impact on utilization should be minimized. This emergency policy recommendation would require lower respiratory COVID-19 testing if upper respiratory testing results are negative.

<u>Summary of discussion:</u>

The Vice Chair shared that most lung programs within his donor service area are accepting lungs without a COVID-19 negative bronchoalveolar lavage (BAL) test. While some donor hospitals may not want to cooperate with a BAL testing on a DCD donor, the Vice Chair anticipated most issues with lower respiratory testing will instead be a result of lack of access. The Vice Chair continued that some

accessibility issues can be circumvented, such as having larger or university hospitals perform BAL testing in the event that smaller donor hospitals don't have access. Other members agreed that most lung transplant programs were requesting lower respiratory testing prior to acceptance as common practice.

One member confirmed with Staff that the OPTN data showing 30 percent of lung donors with lower respiratory testing included those who had deep tracheal aspirates. Another member confirmed that tracheal aspirates would be accepted as lower respiratory samples under the proposed emergency policy. The Chair of the Data Advisory Committee reassured that lower respiratory sample would be defined as tracheal aspirates and anything below.

One member remarked that the ability to allocate lungs prior to lower respiratory results would be critical, particularly for rural donor hospitals faced with greater challenges getting timely results. However, having the lower respiratory results prior to organ recovery or the arrival of recovery teams is in the best interest of all parties. The member expressed that most OPOs would not expect or desire to bypass a lung program that wanted to wait for full results before acceptance, unless it was an extreme circumstance. Another member agreed, noting that the emergency policy should include a provision allowing the OPO to bypass a center in unique circumstances, such as when situational constraints or urgent issues with the abdominal organs preclude further delay of organ recovery. Other members agreed that they expect most OPOs would do their best to accommodate requests for negative results before full acceptance.

A member noted that most OPOs have begun improving access to lower respiratory testing, but not every OPO may have the ability to implement lower respiratory testing for all lung donors emergently.

The Committee agreed most donor hospitals are able to get a lower respiratory sample, even if they are not able to perform the testing. The Committee also reached consensus that gaps in testing, performing, and sampling are currently being resolved by OPOs trying to accommodate widespread requests for lower respiratory testing amongst lung programs.

2. Public Comment Review: Clarify Multi-Organ Allocation Policy

The Committee reviewed public comment trends and feedback, and discussed potential post-public comment changes to the proposal. The Committee also reviewed Final Rule requirements for consideration and further discussion at the next meeting.

Data summary:

The Clarify Multi-Organ Allocation Policy proposal was generally supported, with the understanding of future work towards improved multi-organ allocation policy.

The proposal received several substantial written comments, which expressed the following general themes:

- Concern for kidney alone, liver alone, and kidney pancreas candidate access
    - In particular, medically urgent and high MELD/PELD liver patients as well as high cPRA, low EPTS, and pediatric kidney candidates
    - Support for further analysis on anticipated outcomes and close monitoring for liver, kidney, and KP patient access
- Eligibility criteria and safety net policies
- Expansion of adult heart criteria to include status 4 heart patients, congenital disease and Fontan physiology patients
    - Expansion of pediatric heart criteria to include status 2 pediatric candidates

- Expansion of lung criteria to include lung candidates 0-11 years old (no lung allocation score)
- Priority for multi-organ allocation should be driven by a clinical variable, such as waitlist mortality or life years
- Indication of priority for multi-organ combinations between match runs
- Inclusion of "required" and "permissible" indicators on match run
- Clarification for triple multi-organ candidates and reallocation of second required organ according to released organ policy

The Workgroup reviewed the OPTN Final Rule for consideration with post-public comment changes to the proposal, particularly that this policy:

- Is based on sound medical judgement
- Is designed to avoid wasting organs
- Shall be designed to… promote the efficient management of organ placement

The Final Rule requires the OPTN to "consider whether to adopt transition procedures" whenever organ allocation policies are revised. Before public comment, the Committee did not identify any populations that may be treated "less favorably than they would have been treated under the previous policies if these proposed policies are approved by the Board of Directors, and does not recommend any particular transition procedures. If this statement does not remain the same, the Committee must provide rationale.

Summary of discussion:

The Vice Chair noted there were very few, if any lung-kidney and lung-liver patients under 12 years old over the last few years, and that there were likely few similar heart multi-organ patients. The Vice Chair continued that including pediatric heart and lung under 12 years old would be appropriate and acceptable. Other members reached consensus to include these pediatric patients, particularly as these pediatric multi-organ transplants are so infrequent but are individually very beneficial.

The Vice Chair remarked that expanding heart criteria to status 4 may not be well supported, particularly from conversations within the interdisciplinary multi-organ workgroup. Another member agreed, adding that allocating a liver that far down the heart list would likely take a liver away from a much sicker liver patient. The Chair agreed, remarking on the balance required within the policy to protect both heart multi-organ patients' and kidney and liver candidates' access.

One member noted that there was understandable reasoning to include heart status 4, but that it should be revisited in later multi-organ policy revision. The Chair agreed that future work could better address heart status 4 candidates, and added that it was still permissible for an OPO to offer out a status 4 heart kidney or heart liver. Another member suggested evaluating the impact on heart status 4 multi-organ candidates within the monitoring plan to better acknowledge the concern.

3. Public Comment Review: Modify Deceased Donor Registration

The Committee reviewed public comment trends and feedback, as well as Final Rule and NOTA requirements for further discussion about post-public comment changes at the next Committee meeting.

Data summary:

This proposal was well supported to improve data collection and update the deceased donor registration form. There was general support for the proposed changes around cocaine and other drug use information, but mixed responses to several areas where feedback was requested, including clinical

infection confirmed by culture, Chagas and tuberculosis (TB) history, cancer free interval, and citizenship. Several professional societies submitted substantial public comments, addressing data points where feedback was requested.

The Association of Organ Procurement Organizations (AOPO) was supportive of the proposal, and recommended the following:

- Only collect cross clamp date and time
- Keep citizenship data point
- Update the list of medications, along with dosages and duration of administration of medication
- Collect the number of transfusions, type, and total volume
- Illicit drug usage questions should be modeled in line with the universal donor risk assessment questionnaire
- Due to low incidence of Chagas and TB, no changes are needed
- During a DCD organ recovery, systolic and diastolic blood pressures and O2 saturations should be recorded at a minimum every 10 minutes after extubation
- All cultures collected from a potential organ donor, which have growth other than normal flora, should include sensitivities

The American Society of Transplantation (AST) provided the following feedback:

- Support removal of tattoo questions
- Keep cancer free interval
- Support removal of recovery date
- Maintain citizenship information
- Donor management:
    - Transplant staff typically do not use the information in the DDR
    - Current list appears comprehensive enough
    - Dosages and duration should be collected
    - Consider extending timeframe longer than 24 hours
- Recommend proceeding with recommended changes but include a separate statement to indicate the total volume within the last 24 hours prior to cross-clamp or recovery. For pediatric donors, volume of transfusion is preferred instead of number of transfusions
- Do not collect additional information on clinical infections confirmed by culture at this time
- Support proposed cocaine and drug use chairs
- Unnecessary to add data to assess for specific risk factors for Chagas and TB history, as current demographic information could be interpreted
- Serial data should continue to be collected every five minutes during organ recovery

The American Society of Transplant Surgeons (ASTS) made the following recommendations:

- Support the collection of only cross-clamp date and time
- Citizenship is useful to collect, but a “prefer not to answer” response option should be added
- Donor management – medications listed are standard in donor management “bundle” – dosages and timeframes add laborious work with little clinical impact. Most of this information is collected elsewhere
- Support change to number of transfusions, as it is helpful to know volume within 24 hours of procurement
- Agree with proposed cocaine and drug use changes

<u>Summary of discussion:</u>

A Workgroup member expressed agreement with the ASTS's feedback on donor management, particularly because that information is often not very relevant.

The Workgroup had no further comments or questions.

Next steps:

Staff will continue to compile public comment feedback for each data element for Committee discussion and decisions on any minor necessary post-public comment changes. The Committee will review and discuss this feedback at the April 15 meeting to finalize recommendations to send to the Board of Directors for approval in June.

Upcoming Meetings

- April 15, 2021 – OPO Committee Virtual "In-Person" Meeting (teleconference)

Attendance

- **Committee Members**
  - Diane Brockmeier
  - Kurt Shutterly
  - Bruce Nicely
  - Catherine Kling
  - Chad Trahan
  - David Marshman
  - Debra Cooper
  - Helen Irving
  - Jeffrey Trageser
  - Jillian Wojtowicz
  - John Stallbaum
  - Larry Suplee
  - Mary Zeker
  - Meg Rogers
  - Sue McClung
  - Lara Danziger
- **HRSA Representatives**
  - Marilyn Levi
  - Raelene Skerda
  - Shannon Taitt
  - Vanessa Arriola
- **SRTR Representatives**
  - Bryn Thompson
  - Donnie Musgrove
  - Matthew Tabaka
- **UNOS Staff**
  - Robert Hunter
  - Kayla Temple
  - Alice Toll
  - Courtney Jett
  - Darby Harris
  - David Klassen
  - Kristine Althaus
  - Matthew Prentice
  - Susan Tlusty
  - Nicole Benjamin
- **Other Attendees**
  - Ricardo La Hoz
  - PJ Geraghty
  - Lara Danziger-Isakov
  - Marian Michaels