

**OPTN/UNOS Ethics Committee
Meeting Minutes
April 9, 2018
Chicago, IL**

**Elisa J. Gordon, PhD, MPH, Chair
Keren Ladin PhD, Vice Chair**

Introduction

The Ethics Committee met in Chicago, IL on April 9, 2018 to discuss the following agenda items:

1. Workgroup breakout sessions
 - Multi-organ Allocation Guidance Workgroup
 - Eligibility of Intellectually Disabled Individuals for Transplant Workgroup
2. Discussion: Eligibility of Intellectually Disabled Individuals for Transplant led by Teresa Savage, PhD, RN.
3. Current Ethics Committee Projects and Workgroups
4. Update from the Ad Hoc Geography Committee
5. Review of DTAC public comment proposal: *Clarify Informed Consent Policies for Transmittable Disease Risk*
6. Report on Workgroup Activity (other committees)

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

1. Workgroup breakout sessions

- Multi-organ Allocation Guidance Workgroup members, primarily spent their time working on a data request with the UNOS research staff. The discussion resulted in a finalized data request that includes the following:
 - Demographics of the recipients of solitary kidneys compared to those who receive a kidney via Multi-Organ Transplantation (MOT). This should include at a minimum sex, race, age, calculated panel reactive antibodies (CPRA), blood type, time on the wait list, economic data)
 - Creatinine alone and glomerular filtration rate (GFR) as well (Are many kidneys going to candidates with normal GFR and creatinine)?
 - For liver-kidney, please provide data for the entire group and break this down by the model for end-stage liver disease (MELD)
 - For heart-kidney, please provide data for the entire group and break this down by status on the wait list (using both the new and old status systems if possible)
 - Average kidney donor profile index (KDPIs) of the kidneys for each group (i.e. by MELD range, or heart status)
 - Creatinine alone and GFR
 - Who would have gotten that kidney (next person on the match) for the kidney that went to the MOT candidate?
 - Rate of removal from the wait list for any person awaiting MOT due to death, recovery (no longer needs a second organ) or being too ill (2, 7)
 - Wait list mortality for patients listed for MOT, by type of MOT they are waiting for
 - Post-transplant patient and graft survival (including 3-month survival if that information is known) Similar patients= similar MELD, similar status scores KDPI, blood type at transplant, etc.

- The rate of sharing for isolated kidneys and kidneys that are part of MOT, by DSA, region and/or nautical miles. For instance, the number of MOs that are national shares versus local
- Matched recipients for single organ and MOT (by age, sex, race, blood type) – does the KDPI differ between the groups?
- Eligibility of Intellectually Disabled Individuals for Transplant Workgroup members focused primarily on the scope of the white paper and a review of several articles provided in the meeting agenda. They plan to begin monthly conference calls to work on the white paper and establish a timeline.

2. Discussion: Eligibility of Intellectually Disabled Individuals for Transplant led by Teresa Savage, PhD, RN.

Summary of discussion:

Dr. Savage's presentation centered on the following topics surrounding the eligibility of intellectually disabled individuals for transplant:

- Intellectual disability definition
- Issues of consent
- Allocation decisions

She began by discussing the history of terminology that was used to identify individuals with intellectual disabilities and how it has changed over the years. She then moved on to the criteria that transplant programs use to determine if a potential candidate has an intellectual disability, including:

- Cognitive development
- Academic progress
- Academic level

She then offered the following “take-aways:”

- The determination that a child or adult has an intellectual disability is a process that should involve experts in intellectual disability, input from people who know the child or adult and can speak to their skills and challenges, and assessments over time to capture optimal performance
- Once the “IQ” and adaptive behavior have been assessed, then there should be identification of supports currently in place and supports that would be needed.

Another issue that Dr. Savage presented was the issue of consent for these individuals. Because many adults with I/DD do not have guardians, and often parents erroneously assume that because their adult child has I/DD, they remain the legal guardian. And some providers continue to let parents sign consents and authorize medical treatment. Other issues include:

- Some adults have legal guardians but are probably capable of making their own health care decisions.
- Some families do not want the adult with I/DD involved in health care decisions.
- Some guardians are relatively absent from the lives of their wards.

A person with the intellectual disability should be involved in decisions regarding their health care to the extent of their abilities. Savage noted research that says “Capacity can improve with experience and education” (Kripke, 2016, p. 445) and the *Savage et al.* study exploring end-of-life care for people with intellectual/developmental disabilities revealed that often family members do not want to involve the person with I/DD in order to protect them from frightening

information, or they do not believe the person has the capacity to participate in health care decisions. Medical staff remarked that they often disagreed that the person was incapable of participating but respected the guardian or family's wishes.

A committee member asked Dr. Savage if there was any data regarding differences in capacity as children aged into adulthood. Dr. Savage commented that she was not aware of any data, but she did say that Art Caplan had provided comment in the past that teens are more rebellious and have worse outcomes in general. She said she would hope that family support systems would be considered for those with intellectual disabilities in addition to their age. She understands the concern, but says that this should be looked at on a case-by-case basis.

Another question asked if a prior history of non-compliance should be held against the individual? Is that what you are saying? Is that your view, the committee member asked. She responded that she would want a little more information. For example, people with mobility problems and transportation issues should not be ruled out because they miss an appointment. It depends on whether you can hold the person accountable. People with intellectual disabilities should get the same consideration.

Another member asked how can they be held accountable given their disability? These are pretty difficult questions.

Question: Let's assume that you can't hold them accountable but do you hold them accountable based on their caregivers or support system? And I really mean culpable, Do we exclude them because of their support system? Answer: Can you help them by giving them a better caregiver? Or move them to a better environment? Can you remove guardianship in order to protect someone or change the situation when a caregiver cannot comply with the regimen? But you should ask what other resources could be made available.

Do you see any differences between the intellectually disabled and the cognitively disabled? Answer: I see them differently because they have different life experiences. Someone who is intellectually disabled versus someone who was normal their entire life but becomes cognitively disabled due to an event later in life. I see them as different.

But what about in terms of ethical issues and organ allocation? Probably the same questions about support and the ability to comply.

The Committee took a lunch break after the discussion.

The Committee reconvened after lunch and began the meeting by giving the outgoing members certificates and thanking them.

3. Current Ethics Committee Projects and Workgroups

The Committee then moved on to providing updates on their current projects, including the current white paper on manipulation of the waitlist priority. Each of the workgroups also provided updates as follows.

Multi-organ Allocation Guidance Workgroup

There are two workgroups: the Multi-Organ Allocation Guidance reported that they worked on their data request with a UNOS research analyst. They finalized the following items to include in the data request:

To perform an ethical evaluation of multi-organ transplantation, it is necessary to know who is getting organs via MOT and who is missing out on those organs because they are taken out of the system. The initial review of the information will focus on kidneys in adult patients undergoing simultaneous multi-organ transplantation since kidneys are the most common organ

involved in MOT, and the initial ethical analysis is going to focus on adults only. If feasible, Research will provide data that only includes the time when KAS was active.

Data that we need included:

- Demographics of the recipients of solitary kidneys compared to those who receive a kidney via MOT. This should include at a minimum sex, race, age, CPRA, blood type, time on the wait list, economic data) (1, 4, 5) Creatinine alone and GFR as well (Are many kidneys going to candidates with normal GFR and creatinine)? Research that was sent this morning has some support for this in SLK recipients.
 - For liver-kidney, please provide data for the entire group and break this down by MELD
 - For heart-kidney, please provide data for the entire group and break this down by status on the wait list (using both the new and old status systems if possible) (NEW status may not yet be possible; research staff will confirm.)
 - Average KDPIs of the kidneys for each group (i.e. by MELD range, or heart status)
 - Creatinine alone and GFR
 - Who would have gotten that kidney (next person on the match) for the kidney that went to the MOT candidate?
- Rate of removal from the wait list for any person awaiting MOT due to death, recovery (no longer needs a second organ) or being too ill (2, 7)
 - Wait list mortality for patients listed for MOT, by type of MOT they are waiting for
- Post-transplant patient and graft survival (including 3-month survival if that information is known) (5, 7) Similar patients= similar MELD, similar status scores KDPI, blood type at transplant, etc.
- The rate of sharing for isolated kidneys and kidneys that are part of MOT, by DSA, region and/or nautical miles (3) For instance, the number of MOs that are national shares versus local
- Matched recipients for single organ and MOT (by age, sex, race, blood type) – does the KDPI differ between the groups? (1, 4, 6)

Questions that need to be addressed

- 1) Organ "pulling" - Are some groups more disadvantaged when organs are pulled than others?
- 2) Lack of options in MOT – Do MOT candidates have higher rates of mortality because they cannot undergo some of the bail-out options available to some single organ patients?
- 3) Regionalization – are there areas of the country that are disadvantaged by MOT?
- 4) Protected subgroups
- 5) Fairness to those awaiting single organs
- 6) Standardization of criteria for MOT
- 7) Degree of need and MOT

This data request was reviewed and endorsed by the entire Committee for submission.

The Intellectual disabilities workgroup reported that they had a productive discussion on the complex issues and would move forward on the project with setting up monthly conference calls to continue their work.

Manipulation of the Waitlist Priority White Paper

Feedback has been very positive. The Chair reported that since public comment the only changes that were requested were from staff, including the removal of the context of current policies and place it in the background section. There were other minor, non-substantive grammatical changes.

A committee member asked about the versions that were sent for review. The liaison reported that the version sent out an hour ago is the most recent version for the vote. She explained that today we are only voting on the content of the white paper.

A member had a question about the definitions section, line 75. The second paragraph, we are basically trying to define what we're talking about and the second paragraph talks about a discussion with the liver committee and I thought this was confusing. The Chair commented that this was trying to define things according to what they are and what they're not.

Regarding a cite for the length of time that a person waits at status 1A, a suggestion was made to say instead that "It is not uncommon for a status 1A candidate to wait as long as six months," if we cannot find a cite for an average current waiting time.

The Policy Manager decided that the vote would occur with the understanding that if we can find data or a citation to support the average time for status 1a candidates we would add that cite, and if not, we would phrase it as above.

Another comment was made to be sure to include the comments between the citations (line 38). A committee member made a motion to move the paper to the Board for consideration in June. The Committee voted unanimously to move the paper forward to the Board, 16-0.

The Committee took a short break and then moved on to an update from the Ad Hoc Geography Committee.

4. Update from the Ad Hoc Geography Committee

The Geography Committee's Liaison and UNOS Policy Analyst, provided an update on the Ad Hoc Geography Committee's work. He informed the Committee about the Geography Committee's charge is very clear and limited to discussions and recommendations.

The charge for the Ad Hoc Geography Committee is to:

- Establish defined guiding principles for the use of geographic constraints in organ allocation
- Review and recommend frameworks/models for incorporating geographic principles into allocation policies
- Identify uniform concepts for organ specific allocation policies in light of the requirements of the OPTN Final Rule

The liaison also shared the Committee roster, noting that there was a representative from most of the other committees to represent diverse perspective.

An Ethics member asked why there are two Thoracic committee members on the roster? The liaison reported that that is because they are currently working on a geography issue and also that one of the representatives is a heart specialist and one is a lung specialist.

He also shared the goals of the Committee, including that the Committee will:

1. Discuss and establish defined organ distribution principles for the use in geographic constraints for all organs
2. Review and recommend organ distribution frameworks/models using defined principles

3. Identify concepts that meet the requirements of the Final Rule
4. Report recommended organ distribution frameworks to the Executive Committee and Board of Directors

He also reported what the committee will NOT do to alleviate some confusion in the community about the authority of this Committee. The Committee will not...

- Tell other committees what to do
- Change allocation policies
- Send proposals for public comment
- Work in isolation

The liaison wrapped up the presentation by explaining the difference between allocation versus distribution, explaining that distribution is one part of allocation. Distribution includes the geographical components, while allocation also includes urgency, access to vulnerable populations, and outcomes.

He then shared what will be included in the recommendations report, including the development of ad hoc committees, the principles of organ distribution, thematic models, and suggestions for next steps. He reminded the group that the Board has the authority to determine the next steps, not the Geography Committee.

A committee member asked the liaison to provide an example of a principle. He said that one of the principles under consideration is that organs should be viewed as a national resource while another principle (conflicting) is that organs should be viewed as a community, or local, resource before going out nationally. Also, there were several principles that revolved around travel. If one principle says we should distribute as broadly as possible, then how does work with another principle that says we have to take into account travel time (and costs)?

The Chair asked the liaison if he could share with the committee the progress that they've made thus far. The liaison reminded the group that the meeting minutes are up on the OPTN website. As far as the principles, he reported that they have not changed much since their in-person meeting. The over-arching principle is that any geographic constraints that you put on distribution must be rational and consistently applied. Meaning, the constraints must be defensible and evidence-supported. This is the over-arching principle we're looking at, and an important one for the Ethics Committee to hear about. There was also a lot of discussion about modelling... ideas, variances that have existed in the past, and other data that we need. The models were weaned down to six or so.

Someone asked what the specific imperative or main goal is. The liaison answered that it was to get consistency across all organs about how we look at distributing organs.

Was the committee able to identify a principle that applies to all organs? Principles have been able to be applied across all organs, but not models yet, he reported. We are still working on that.

5. Review of Ad Hoc Disease Transmission Advisory Committee (DTAC) public comment proposal: Clarify Informed Consent Policies for Transmittable Disease Risk, DTAC Chair

The Committee Chair of the Disease Transmission Advisory Committee, presented their public comment proposal on clarifying informed consent policies. He provided an overview of the proposal, including the problem the proposal solves and what the proposed solutions are, including the post-public comment changes under consideration by the committee.

Discussion:

The Ethics Chair started the discussion by pointing out that there are no changes for increased risk requirements; is that because it's already covered under the consent requirements? The DTAC Chair answered that it's a great question, because according to current policy to become an increased risk donor you have to have a behavior that occurred in the last 12 months. So you could have a donor that may have acquired Hepatitis C 20 years ago and there is nothing that would put them in an increased risk category so there is nothing in current policy that would cover that. Hep C positive and increased donor risk; currently we require consent for an increased risk donor but not Hep C positive.

A committee member further commented that this used to be a huge issue (no Hep C positive informed consent requirements). But a year ago; a couple, or about 10, people were knowingly given kidneys that were Hep C positive and 10% were cured within 12 weeks so that should be considered. For HIV, as with Hep C, we have to consider if the risk of infection and that these diseases are now curable/manageable, may be better than being on dialysis. The DTAC Chair agreed with that, and added that PHS is a pretty blunt instrument, it's a harder discussion with a kidney since they can stay on dialysis but for an organ like a heart, they may not be able to wait for a better organ, a non-increased risk organ. But even with Hepatitis C, the risk is still very low for increased risk donors.

Another question: Did your committee specify information for that population (Hep C positive organs) at the point of organ offer? We haven't been specific to say they need to do that when the patient is listing, but the time to do it is at the time of offer. To do it efficiently, you should have done this ahead time.

And finally a committee member asked what about Hep C to Hep C? Or HIV to HIV? Does this requirement still apply? Yes, we grappled with that. With HIV, you have to consent them to be a HOPE Act participant so that's taken care of. With Hep C, that's less clear. Even if you as a group feel that the difference or risk is incredibly small, from the policy point of view, we decided it was better to say they had to do it across the board.

6. Report on Workgroup Activity (other committees)

Committee members serving on other committee projects (not sponsored by Ethics Committee) provided a brief update on their work:

- A report on the KPD Deceased Donor Chains workgroup
- A report on the Kidney Committee's Pediatric Access workgroup

After these reports, the meeting adjourned.

Upcoming Meetings

June 21, 2018 Conference Call