OPTN Ethics Committee
Meeting Summary
August 20, 2020
Conference Call

Keren Ladin, PhD, Chair
Andrew Flescher, PhD, Vice Chair

Introduction

The Ethics Committee met via Citrix GoToMeeting teleconference on 08/20/2020 to discuss the following agenda items:

1. Align OPTN Policy with U.S. Public Health Service Guideline, 2020 Proposal
2. Update on the Continuous Distribution of Organs Project
3. Other Business

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

1. Align OPTN Policy with U.S. Public Health Service Guideline, 2020 Proposal

Marian Michaels, ex officio member of the Ad Hoc Disease Transmission Advisory Committee (DTAC), provided an overview of the *Align OPTN Policy with U.S. Public Health Service Guideline, 2020* proposal currently in public comment.

Summary of discussion:

The U.S. Public Health Service (PHS) has provided guidance on the prevention of donor transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) infection for many years. This U.S. Public Health Service Guideline (Guideline) was previously updated in 2013 and put into OPTN policy in 2014. On June 26, 2020, PHS published an updated Guideline for assessing solid organ donors and monitoring transplant recipients for HIV, HBV and HCV infection in the Morbidity and Mortality Weekly Report. These updates followed a request from the transplant community and DTAC to revise the Guideline to more accurately reflect the current risk level of utilizing organs labeled "increased risk" based on availability of improved testing methods, such as Nucleic Acid Testing (NAT), and a more robust risk assessment.

The Final Rule requires that OPTN policies are consistent with the Guideline. The intent of the proposal is to increase the use of organs with a low risk of unexpected infection as well as allow for more contextualization when discussing the risks and benefits of accepting or declining organs from donors with specific risk factors. In addition, it provides a safety back up that promotes early identification of HIV, HBV, and HCV if transmission unexpectedly occurs by focusing on prompt implementation of therapy to minimize allograft damage and mortality.

The rates of donors recovered who were classified as an "increased risk donor" in a given year increased from a low of 7.5% in 2007 to over 27% by 2018 and 2019. Currently, accepting offers from these donors requires a separate informed consent from the potential recipient.

The proposal includes the following:

- Remove label “increased risk donor”
- Shorten timeframe for donor risk criteria assessment from 12 months to one month
- Remove hemodilution as infectious disease risk criteria in policy
- Require deceased donor testing specimens drawn within 96 hours of procurement
- Require living donor recovery hospitals to arrange storage of pre-transplant samples for 10 years
    - This matches current policy for deceased donor samples
- Remove requirement for a separate informed consent when donors meet risk criteria
- Require assessment of need for HBV vaccination during candidate medical evaluation and report vaccination status
- Add required testing:
    - Candidate pre-transplant for HIV, HBV, and HCV during transplant hospital admission but before transplant occurs
    - Universal NAT for HIV, HBV, HCV on all transplant recipients 4-8 weeks after transplant
    - Liver recipient testing between 11-13 months post-transplant for HBV NAT

From an Organ Procurement Organization (OPO) standpoint, the proposal will require the modification of the donor screening assessment for identifying donor risk criteria and repeat tests if procurement does not occur within 96 hours of when infectious disease samples are first drawn.

Transplant hospitals will be required to:

- Complete additional testing for living donors, candidates, and recipients
- Update candidate evaluations to include assessment for HBV vaccination need
- Report reasons HBV vaccination cannot be initiated or completed prior to transplant
- Arrange for living donor specimen storage

DTAC is seeking feedback during public comment from committees and regional meeting attendees.

A member asked if the HBV testing documentation requires evidence that a vaccine has been received or antigen titer evidence that signals the patient responded to the vaccine. The DTAC member responded that because some patients do not respond robustly to HBV vaccines, antigen titer evidence is preferred. The policy does not mandate giving the vaccine but encourages vaccination and the testing of antigen titers to see if a vaccine is needed.

A member raised a concern around the removal of the designation "increased risk" and the change to the informed consent process specific to these donors because the risk is still elevated. They noted that the various factors that are included in this classification have varied levels of risk and is concerned that this elevated risk is adequately and thoroughly communicated with patients. They commented that it would be helpful to review a script outlining the way these conversations will be held. The DTAC member agreed that the education component needs to be strong to assist with hospitals’ communication with patients when discussing risks and benefits.

The Vice Chair commented that they are in favor of this proposal for being altruistic and mathematically astute but has concerns about the potential for an occasion where the consent process is not followed and the outcome for that one recipient is devastating. They noted that the consent process needs to be rigorously developed and followed. A member asked if the communication with the candidate would include a description of why the organs were initially designated “increased risk” and why that designation is being removed. They suggested providing the updated risk information including the rationale for why the risk has been lessened due to the new testing standards. The DTAC member agreed with this suggestion.

A member asked if there would be an additional consent added to the existing paperwork. The DTAC member responded that the current separate “increased risk” consent will be embedded into the consenting process. Patients will still need to be informed but will not have a separate consent form as done currently. A member commented that the amount of informed consent paperwork is overwhelming. They commented that their hospital has an “increased risk” consent section that they highlight to emphasize when discussing risks with patients.

A member who is a transplant recipient raised a concern about patient autonomy and commented that whether there is a 1 in a million risk or not, there still needs to be a conversation with the patient. They are concerned about how patients are communicated with and if the information provided will be adequate for them to make a decision for themselves.

The Chair asked if patients provided input in order to ensure that this population is understanding what is meant when they are consenting to risks. The DTAC member shared that all members are involved in developing the proposal including transplant hospitals, OPOs, patients, living donors, and donor families. DTAC is also reaching out for comments from the Patient Affairs Committee (PAC).

A member commented that having another consent is a lot for the patient when they are going through the consent process and agreed that the terminology “increased risk” could be improved to not be as negative. Another member commented that they are in favor of this proposal as they go through the consent process with a lot of candidates. They noted that the language "removing the consent" included in the proposal raises red flags and would be better received if restated.

Another member who is a transplant recipient commented that they are in support of the proposal. They shared that they value the change from spotlighting one set of factors to having a more complete conversation about all factors that may affect the function of the graft. The DTAC member agreed and commented that it is important to contextualize the risks. A HRSA representative commented that there has been a lot of discussion around the language of "increased risk" because it may discourage the acceptance of the organ which limits a recipient’s access to the benefits of accepting it. There will be ongoing autonomy for the patient throughout the consent process. During the clinic visit when the consent is signed by the patient there will be informational materials available. The patient will get to choose whether or not they accept an organ from a donor with certain risk factors.

The Chair asked for the best way to provide feedback. The DTAC member responded that the Committee members can reach out individually but encourages posting public comment responses. UNOS staff encouraged anyone on the committee to submit public comment as individuals. There will be a comment made on behalf of the committee that synthesizes the discussion held.

A member raised a concern that the requirement to store living donor recovery specimens for ten years may create a barrier for potential living donors, especially minorities, who may be hesitant to consent to this practice because of institutional distrust.

Next steps:

Members are encouraged to review the proposal in more detail and post public comment responses. A group response will be posted after approved by Ethics Leadership.

2. Update on the Continuous Distribution of Organs Project

James Alcorn, UNOS Senior Policy Strategist, presented an update on the *Continuous Distribution of Organs* project, sponsored by the Lung Transplantation Committee. Although feedback is requested, this is not a policy proposal.

Summary of discussion:

UNOS staff described Continuous Distribution as a new way to allocate organs and develop organ allocation policies. He shared that Continuous Distribution allows transparent and structured conversations about equity versus utility in organ allocation noting that previous allocation projects commonly hit barriers relating to how to best structure conversation when assessing the balance of various ethical principles.

In Continuous Distribution for lungs, the following attributes and associated goals contribute to composite allocation score.

- **Medical urgency** – prioritize the sickest candidates first to reduce waiting list mortality
- **Post-transplant survival** – prioritize candidates who are expected to survive for at least one year after receiving a transplant
- **Candidate biology** – increase transplant opportunities for patients who are medically harder to match such as sensitized patients or patient height for lung
- **Patient access** – increase transplant access for patients under the age of 18 and patients who previously donated an organ or part of an organ
- **Placement efficiency** – consider resource requirements required to match, transport, and transplant an organ

Continuous Distribution aims to create a very transparent way to discuss prioritization when balancing these goals. The Continuous Distribution team collaborated with experts in the field of operations to apply a multi-criterial decision making model to organ allocation. After meeting with these experts, it was concluded that the most appropriate methodology to use is the Analytic Hierarchy Process (AHP). AHP uses pairwise comparison to determine value preferences between two attributes such as "decrease waitlist deaths" and "improve post-transplant survival." Members of the transplant community are invited to participate in this process by stating their preferences which will inform a composite weight for the attributes.

UNOS staff noted that the way in which to rank a candidate's medical urgency clinically or the distance between the donor and candidate hospital is already known. These existing rankings will receive weight in addition to the weight determined for the Continuous Distribution attributes. This way, the balance of utility and equity as well as other ethical principles may be measured mathematically.

UNOS staff encouraged the committee to review the Continuous Distribution paper that is posted on the OPTN website to learn more about the methodology. Committee members will receive an email from Decision Lens to participate in the attribute preference exercise. This link can be shared with anyone to invite them to participant, not just members of the transplant community.

The Chair commented that AHP is a very interesting methodology and asked if input has been limited to members of the transplant community or also includes the donor and the potential patient community. UNOS staff responded that the broader transplant community has been invited to contribute including those on the waiting list, donor families, lung recipients, and transplant candidates. Demographics are being collected to be able to review the results in cluster analyses. The Chair suggested including members of the general public. The Chair commented that ethicists who work on priority problems consider the value of public opinion in these matters especially when determining which attributes to assess. UNOS staff noted that the paper outlines why these attributes were selected. The results of the AHP exercise will be considered along with regulatory requirements, committee discussion, and other inputs before proposing policy.

<u>Next steps:</u>

Committee members will receive an email with a link to participate in the AHP exercise. The Committee will provide feedback to UNOS staff.

3. Other Business

The Chair shared that the General Considerations in Assessment for Transplant Candidacy (CAT) Rewrite paper will be discussed at the next Committee meeting and asked members to review the draft included in the meeting materials and send comments.

Next steps:

Committee will review and provide feedback on CAT Rewrite draft to UNOS staff and Ethics Leadership.

Upcoming Meeting

- September 17, 2020

Attendance

- **Committee Members**
  - Aaron Wightman
  - Amy Friedman
  - Andrew Flescher
  - Catherine Vascik
  - Colleen Reed
  - David Bearl
  - Earnest Davis
  - Elisa Gordon
  - George Bayliss
  - Glenn Cohen
  - Keren Ladin
  - Lynsey Biondi
  - Mahwish Ahmad
  - Michael Davis
  - Roshan George
  - Sanjay Kulkarni
  - Tania Lyons
- **HRSA Representatives**
  - Chris McLaughlin
  - Jim Bowman
  - Marilyn Levi
- **UNOS Staff**
  - Emily Ward
  - James Alcorn
  - Kaitlin Swanner
  - Kiana Stewart
  - Sarah Konigsburg
  - Susan Tlusty
- **Other Attendees**
  - Marian Michaels