OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

OPTN Ethics Committee
Meeting Minutes
April 8, 2019
Chicago, IL

Elisa Gordon, MPH, PhD, Chair
Keren Ladin, PhD, Vice Chair

Introduction

The Ethics Committee (the Committee) met in Chicago, IL on 04/08/2019 to discuss the following agenda items:

1. Update on Intellectual Disabilities Project
2. Multi-Organ Transplant White Paper
3. New Project Breakouts & Discussion
4. Intellectual Disabilities Project Discussion

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

1. Update on Intellectual Disabilities Project

A presenter from UNOS staff and HRSA staff provided an update on the coordination of the Ethics Committee project and the Office of Civil Rights (OCR) pending guidance.

HRSA and the OCR requested a memo from the Ethics Committee outlining some of their thoughts and concerns on the issue of intellectual disability and evaluation for transplant.

Summary of discussion:

One committee member asked if there was any insight as to the details of the OCR guidance. The HRSA representative explained that they did not have many details. A Committee member asked what sparked OCR's interest in this topic. The HRSA presenter did not have any details. One committee member asked if there were certain details about the Committee's paper that sparked the initial mandate to pause work on the paper. The HRSA presenter relayed that there were not specific concerns in the paper but rather the issue was one of timing and coordination with the OCR.

One member asked what the goal of the OCR guidance is in order to provide the most helpful memo. The presenter from HRSA did not have specific details. One member asked regarding the timeline for the memo. The HRSA representative did not have details regarding the timeline of the memo and resulting OCR guidance. The UNOS staff presenter recommended that the workgroup focus immediately on creating a memo and aim to provide it to the OPTN Executive Committee at the next possible meeting. The same member also wondered what length and depth is expected of the memo. The UNOS staff presenter suggested the Committee focus on extenuating circumstances, support network and the other nuances of the topic.

One member asked if the OCR had already been provided with a full draft by the workgroup. The HRSA presenter shared that at this time it did not seem that the OCR had a full draft copy of the workgroup. Several committee members spoke in concern of a rough draft of a paper that had not been voted on by the workgroup shared as a public record. One member spoke in support of sharing a very high level view of the issue during the memo. Another member spoke in support of better understanding what aspects of this subject might be considered too controversial to address so the Workgroup can make sure to avoid them.

Several workgroup members spoke up in frustration of the work of the committee being shut down. The UNOS presenter pointed out the importance of consistency of guidance to the transplantation community. One member pointed out that the goal of the Ethics Committee is to provide an ethical opinion from experts on multiple subjects. The UNOS presenter indicated that the scope and purpose of the Ethics Committee may not cover any and all subjects in the transplantation community due to the fact that the ethical guidance issued by the Committee and approved by the Board represents the position of the OPTN. One member asked for future written sign off by HRSA for future projects. The member asked if there was a lot of value in continuing to work on the white paper after OCR's guidance has come out. Another member felt that the best product would be a strong collaboration from the OCR and the Ethics Committee. Another member seconded collaborating with OCR and that the two groups should collaborate. One UNOS staff member spoke in strong support of increasing communication between HRSA, OCR and the Committee.

Next steps:

HRSA will have a meeting with OCR to coordinate on the next steps.

2. Multi-Organ Transplant White Paper

A UNOS presenter gave an update on the public comment of the proposal and progress to go before the board. The committee went through the paper to review and discuss edits.

Data summary:

All the regions overall supported the proposal. Region 11 had the most negative reviews of the proposal.

ASHI and AST both provided comments supporting the paper.

Pancreas Committee was strongly in support of treating KP transplants different from other multi-organ combinations for the following reasons:

- About 80-85% of pancreata used in Kidney-Pancreas (KP) transplants and therefore less likely than other MOT to be used as solitary transplant and more likely would be discarded
- KP transplants address one disease
- In many cases, kidney is the primary organ and pancreas is supplementary – not the case for other MOTs, and counters the assumption that KPs are unnecessarily pulling kidneys
- Current KP allocation system already has minimum requirements, collects data/reviews outcomes, identifies impact on quality of life year benefit (QALY) and long term survival, and establishes priority of KP in relation to single organ transplant alternatives

Summary of discussion:

One member commented on the importance and significance of updating the older Ethics white papers. Another member spoke about adopting a process to review past work for currency more regularly.

The Committee discussed some of the nuances of the term "life-saving" and the differences between acutely ill and those candidates who can either sustain themselves longer or receive a single transplant as opposed to a multi-organ combination. The members discussed the grey area of diagnosing when adding a kidney to a multi-organ transplant that is for life-saving purposes as opposed to those whose kidneys could recover function. The Committee decided

to note in the paper that all mentions of “life-saving” are intended as “immediately life-saving” unless otherwise specified.

The Committee discussed modifying a newly added paragraph in the introduction that describes the impact of KP prioritization at the local level on SOT candidates. The Workgroup leader spoke in support of removing a sentence on local prioritization disadvantaging SOT candidates since this is discussed in Section G: MOT and Protected Subgroups. The rest of the Committee agreed and the change was made.

The UNOS presenter pointed out a concern about using the term “fair-innings” principle as it is unclear if the OPTN has endorsed this principle. One workgroup member pointed out that the Ethics Committee, draws on multiple ethical principles – some of which conflict. The Committee chose to strike language using the word “endorse” in the introductory section to the ethical dilemmas.

The Committee discussed ways to modify the current graphics depicting the allocation of multi-organ combinations to candidates on the list before deciding to eliminate certain graphics entirely, finding that the graphics did not add clarity but made the section more confusing.

The Committee modified the description of “cherry picking” or pulling organs to use a more neutral term of “redirecting”.

The Committee discussed the exact recommendation of Section D and whether a recommendation of the national review board should be for all MOT exception candidates. The Committee went back and forth on whether or not it was prudent to include a recommendation for a national review board for MOT. One committee member explained how the heart exception review process worked in regards to this issue. The Committee agreed on keeping a recommendation for a national MOT review board but added qualifying language.

The Committee clarified impact by geography by removing the term “co-localizes” and replacing it with: “ensures the harm is not in the same geographic area”.

The Committee discussed a paragraph on pediatric donor organs. The Committee agreed to clarify a sentence stating that “pediatric donor organs do not exclusively go into pediatric candidates, which may limit the pool further”, due to the fact that some pediatric donor organs are first offered to pediatric candidates. However, the Committee did note that pediatric patients may be disadvantaged by the prioritization of MOT at the local level, depending on the organ.

The Committee added some qualifying language regarding a comparison of SOT and MOT outcomes.

The Committee removed some newly added language that lacked a citation.

The Committee voted unanimously (16 votes) to send the current edited version of the paper to the Board.

Next steps:

The Committee will send the revised version of the Multi-Organ Transplant White Paper to the Board.

3. New Project Breakouts & Discussion

The Committee had breakouts and then discussed some of the new project ideas proposed by members.

Summary of discussion:

After the breakouts the Committee reconvened and each of the three breakout groups shared some of their favorite ideas.

* represents votes by committee members for their favorite ideas.

Group 1:

1. Genetic testing of APOL 1 – or broader genetic testing in general**
2. Do we wish to explore the ethical considerations within the context of our current policies/rules for disclosing donor information to recipients?
    a. Do we wish to explore the ethical considerations within the context of our current policies/rules for disclosing donor information to recipients? I suppose this could be true for both the deceased donor/family and for the living donor initially wishing to be anonymous. And, do we provide or need to develop policy when the recipient wants future info about their living donor or donor family?
3. Opt in vs. Opt-out*
4. Undocumented Aliens and reciprocities. These people can become donors but not recipients. Or international residents who can become recipients but not donors.
5. Dead donor rule

Group 2:

1. Setting guidelines for best practices regarding protecting living donors. Principle of paternalism. Analysis of the many issues that arise from non-uniform criteria and setting universal standards.*****
    a. A white paper which calls for uniformity in transplantation centers for criteria of eligibility of donors (e.g. smoking; BMI; etc.).
    b. I'm interested in this issue in terms of not only "requiring/requesting" 2 years of follow-ups from the living donor but more. I understand some work is being done for a registry of living donors and documenting follow-up. Are there ethical considerations that come into play? Not allowing a person to risk their health without some type of follow-up required? Of course, we can't require...so, what next? Do we place some responsibility with the recipient? Do we place some more responsibility with the transplant center? And, what is the ethical responsibilities when/if the living donor does become ill and it is shown related to the previous organ donation? Do we pose the ethical responsibility toward some entity: transplant facility/insurance provider?
    c. Age and living donation to older candidates especially with paired kidney donation*
        i. A member of HRSA spoke up in concern about age discrimination
2. Bob Veatch's idea on balancing utility and equity with the OPTN strategic allocation goals.*
    a. One UNOS staff member explained that the best process would be for the Ethics Committee to write a memo rather than to sponsor a project and any re-assessment of the OPTN strategic goals would be done by the Executive Committee and Board.
    b. The Committee member felt that such a project would analyze how the ethical principles are related to the OPTN strategic goals. The UNOS staff member explained that any such work would be more of an advisory guidance document than a public comment proposal. One member commented that it would be

important before dedicating to the work that there was interest from the internal OPTN.

c. Another committee member suggested that members write an article on the subject as individuals rather than as a committee. One UNOS staff member brought up the importance of conferring with the biggest stakeholder before writing such a paper.

Group 3:

1. White paper on ethical considerations in living donation. Obtaining consent or considering young adults for living donation
    a. Human brains are not fully developed until around age 25. Therefore, how can young adults (age 18-25) give informed consent for living donation? This white paper should evaluate the eligibility of young adult living donors. Should there be a minimum age cut off?
2. Ethical frameworks for non-directed donation**
3. On-site procurement teams
    a. Is this a better topic for the OPO committee to tackle?

Committee Leadership

1. Analysis of different allocation systems of different countries.
2. Re-writing CAT, criteria for transplantation
    a. One UNOS staff member made note of how the forthcoming OCR guidance might have impacts on other transplantation criteria

The Committee discussed a current project by the Living Donor Committee on social media and living donation. Several committee members felt strongly that because the Living Donor Committee project examines ethical analysis of the subject that the Ethics Committee should be strongly involved. One member felt concern about the internal process and the fact that although the Ethics Committee is listed as a stakeholder, they may not be involved in the development of the process.

Next steps:

The UNOS staff members will speak to the staff supporting the Living Donor Committee about collaborating on the social media project.

4. Intellectual Disabilities Project Discussion

The Workgroup leader gave a brief update on the project.

Summary of Discussion:

The Workgroup is seeking more input regarding the support network and social value sections. The Workgroup also would like input regarding the extent to which pediatric considerations should be made. The workgroup leadership brought up the possibility of performing a survey.

Upcoming Meetings

- May 16, 2019 (teleconference)
- June 20, 2019 (teleconference)