OPTN/UNOS Ethics Committee Meeting Summary March 14, 2016 Chicago, IL

Peter Reese, MD, Chair Elisa Gordon, PhD, MPH, Vice Chair

Discussions of the full Committee on March 14, 2016 are summarized below. All committee meeting summaries are available at http://optn.transplant.hrsa.gov/

Committee Projects

1. Imminent Death Donation

The Committee continues to examine the ethical considerations of imminent death donation (IDD).

Imminent death donation has occurred in the past but is currently prohibited under existing policy. Imminent death donation involves the removal of transplantable organs prior to an imminent, planned withdrawal of support expected to result in death and is a donation alternative to donation after cardiac death for patients who are not brain dead. The Committee's focus was on those individuals with severe brain injury. The Committee recommends that the practice of organ donation from such individuals be referred to as "Living Donation Prior to Planned Withdrawal" (LD-PPW) instead of imminent death donation.

The Committee led a work group with representatives from the OPO, Living Donor, and Operations and Safety Committees to investigate this issue.

In late 2015, the work group prepared a report on imminent death donation for presentation to the OPTN/UNOS Board. The report was included in the meeting materials provided to Board members but was not considered by the Board.

In response, the Committee asked nine Committees (OPO, Operations and Safety, Living Donor, MPSC, Kidney, Patient Affairs, Minority Affairs, Transplant Administrators, and Transplant Coordinators) to review and provide formal responses concerning the report.

The Committee reviewed these responses during this meeting. Several themes were identified including:

- Potential lack of support by medical staff
- Need for guidance regarding the timing for presenting option for DCD versus LD-PPW
- LD-PPW would provide an organ donation option for patients not expected to meet DCD criteria
- Potential loss in public trust due to potential violation of the Dead Donor Rule
- Need for modeling to better understand how LD-PPW might impact the total number of organs available for transplant

Based on this review, the Committee determined that the high level of concern for eroding the public trust did not support additional work on LD-PPW at this time. The

Committee supported updating the LD-PPW report to reflect feedback from the nine Committees that reviewed the report. The Committee supported revising the report so it could serve as a white paper and be available to the public through the OPTN website.

2. Ethical Consideration of Multi-organ Allocation

The Committee continued initial work on this project which still needs approval by the Executive Committee of the Board.

Ethical questions exist regarding current multi-organ transplantation (MOT) allocation policies. Under current policy, multi-organ candidates are currently afforded the highest priority in allocation of the non-primary organ(s) and are prioritized before single organ candidates. This is a long standing policy, which has recently been challenged by members of the transplant community. In particular, members have asked whether ethical principles support that other types of transplant candidates should receive higher priority, such as pediatric candidates or highly-sensitized candidates for kidney transplantation.

During the meeting the committee reviewed and discussed liver, kidney and heart lung allocation. The Committee supported the following preliminary parameter to guide future work:

- There should not be particular incentives for MOT e.g. by removing these recipients from report cards from the SRTR
- MOT policies should be transparent, easy to access and easy to understand
- MOT criteria should, to the extent possible, be based on evidence about need and outcomes (avoid wasting organs and futile transplants)
- While MOT candidates are highly disadvantaged, MOT policies should carefully consider effects on individuals also at a great disadvantage – such as children and for kidneys, the highly sensitized.

3. Review White Papers for Accuracy and Relevancy

The Committee has developed a series of white papers on bioethical issues that are available on the OPTN website. Some of the topics addressed in the white papers include:

- An Evaluation of the Ethics of Presumed Consent
- Financial Incentives for Organ Donation
- The Ethics of Organ Donation from Condemned Prisoners

These resources have not been regularly reviewed to ensure they remain accurate and relevant. In response, the Committee has reviewed the white papers for accuracy and relevancy, and has determined if each white paper should be maintained in its current form, is in need of minor or major revision or should be eliminated because it is no longer relevant.

The Committee reviewed the status of each white paper during its spring 2016 meeting and will continue to work on the white papers during a series of monthly conference calls. The Committee plans to have two additional revised white papers ready for Board consideration in June 2016 which will address 1) split liver allocation and 2) presumed consent.

Review of Public Comment Proposals

4. KAS Clarifications and Clean Up Proposal

The Ethics Committee considered this proposal and responds, in most cases, a valid consent is a consent that is obtained in advance of the organ offer. Obtaining consent (for a kidney with a KDPi greater than 85) at the time the organ is offered presents multiple challenges because of the limited time window in which the processes of informed consent may be implemented.

5. Simultaneous Liver-Kidney Allocation Proposal

The Ethics Committee considered this proposal and responds that the proposal would improve existing policy by establishing rules that improve equity, transparency and documentation and rules that are based on objective medical criteria. The Committee is concerned that the proposal may not sufficiently protect or prioritize the most vulnerable candidates on the waitlist, e.g. pediatric and highly sensitized candidates.

Other Significant Items

6. Policy Oversight Committee Update

The vice Chair provided and update on the status of the strategic plan and on the status of current and proposed new projects to be reviewed at the next Policy Oversight Committee meeting.

Upcoming Meeting

• To be determined