

**OPTN/UNOS Ethics Committee
Report to the Board of Directors
June 23-24, 2014
Richmond, VA**

**Alexandra Glazier, JD, MPH, Chair
Peter Reese, MD Vice Chair**

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This report reflects of the work of the OPTN/UNOS Ethics Committee between September 2013 and April 2014.

Action Items

None

Committee Projects

1. General Principles of Pediatric Allocation

The Ethics Committee contributed to the General Principles of Pediatric Allocation project. The project is an update to the OPTN's Principles of Organ Allocation, which the Ethics Committee has updated over several years, with a specific focus on pediatric allocation. The Ethics Committee provided the Pediatric Committee with the framework and background of these principles. For more information, see the **Pediatric Transplantation Committee's report to the Board**.

2. Exhausting the Match Run

The Ethics Committee contributed to this project from the International Relations Committee. Ethics Committee members are participating on a work group considering solutions that would clarify the circumstances determining when allocation cannot be completed in the U.S. and organs can be offered to foreign entities. For more information, see the **Ad Hoc International Relations Committee's report to the Board**.

3. Imminent Death Donation

The Committee has discussed imminent death (IDD) donation during previous meetings and the Chair of the Committee has presented this topic to the Living Donor Committee. Imminent death donation involves the removal of transplantable organs prior to an imminent, planned withdraw 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 has a new proposed project to address the *Ethical Considerations of Imminent Death Donation*. Under this proposed project, the Committee would lead a workgroup with representatives from the OPO, Living Donor, and Operations and Safety Committees to investigate the ethical issues involved in surrogate consent of living donors. This project was recently considered and supported by the Policy Oversight Committee and will be considered by the Executive Committee of the Board in June 2014.

During its March 2014 meeting, the Committee continued preliminary work on this project by developing and approving the following resolution:

The Ethics Committee recognizes that Imminent Death Donation is an emerging donation practice that may be ethical under certain circumstances but understands that significant ethical, clinical and practical concerns must be addressed before policy development can be considered. The Committee therefore recommends that a joint subcommittee be formed including the Kidney, OPO, Living Donation, and Ethics Committee to further explore IDD and address concerns.

4. 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 Informed 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 proposed a new project to Review White Papers for Accuracy and Relevancy. This proposed project was recently considered and supported by the Policy Oversight Committee and will be considered by the Executive Committee of the Board in June 2014.

Review of Public Comment Proposals

The Committee reviewed 3 of 17 proposals released for public comment from March – June 2014.

5. Proposal to Continue the Adolescent Classification Exceptions for Pediatric Lung Candidates (Thoracic Committee)

The Committee supported this proposal but commented that surgeons record if they performed a lung reduction surgery in the patient's chart, so this information could be collected without waiting for programming. There is a need to understand both sides of the utility equation by understanding how frequently a cut down procedure is performed, collecting this data should not be dependent upon programming.

6. Proposal to Modify Existing or Establish New Requirements for the Informed Consent of all Living Donors (Living Donor Committee)

The Committee supported this proposal but questioned why it did not address surrogate consent.

7. Proposal to Notify Patients Having an Extended Inactive Status (Transplant Coordinators Committee)

The Committee supported this proposal and commented that many patients do not understand their status on the waitlist.

Other Committee Work

8. Guidelines for Applying Exceptions Uniformly

The Executive Committee approved an exception for allocation of lungs recovered from adult donors to adolescents (6-11 year old). In response, a work group was formed to consider how exceptions are applied.

Current policy is inconsistent in the application of exceptions across age groups and organ type, and guidance may be needed to help review boards apply exceptions fairly and consistently.

The work group began meeting in January 2014, and is considering if potential guidance on this topic would be in the form of a memorandum, a white paper, or perhaps a statement to the OPTN Board.

9. Preserve the Option to Donate

The Committee had a preliminary discussion regarding the legal requirement to ensure the medical suitability of transplantable organs. In the circumstance of a trauma patient with a non-recoverable brain injury, the medical center and staff are required to maintain the medical suitability of the patient for possible organ donation. Maintaining medical suitability is not clearly defined, but could involve medical tests and interventions such as abdominal surgery, which will not benefit the patient.

Existing statutes require Organ Procurement Organizations (OPOs) to evaluate all potential organ donors, assure that families of potential organ and tissue donors are aware of the option of organ and tissue donation and their option to decline. Existing statutes further require OPOs to conduct any reasonable examination necessary to ensure the medical suitability of a body part that is or could be the subject of an anatomical gift for transplantation, therapy, research, or education from a donor or a prospective donor.

The Committee is not proposing additional work on this topic at this time.

10. Jahi MacMath Case: Implications for Donation and Transplantation

The Committee discussed some of the ethical implications of this recent highly publicized case involving a brain dead fourteen year old girl and the court proceedings addressing removal of life support.

The criteria for brain death is widely accepted around the world. Biological death is based on homeostatic equilibrium (some level of brain activity required to maintain homeostasis). The criteria for brain death and biological death are may be in conflict and do create confusion.

Jahi MacMath may be brain dead but she is biologically alive. Based on the current legal definition of brain death, the hospital caring for Jahi MacMath had a legal right to withdraw life support or to require her family to find another facility to assume the care (and cost of her care). In her case, bioethicists commenting in the media did not differentiate between brain death and biological death.

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Patients in a permanent vegetative state may meet the definition of brain death, but will continue to have some brain activity.

In the future it may be necessary to define human death versus biological death. Will it be necessary to define when a patient is “dead enough” for certain purposes? The dead donor rule prevents organ recovery from anyone who is not “legally dead” but not does address if the donor is also biologically dead.

The Committee is not proposing additional work on this topic at this time.

Meeting Summaries

The Committee held meetings on the following dates:

- October 21, 2013
- March 10, 2013

Meetings summaries for this Committee are available on the OPTN website at:

<http://optn.transplant.hrsa.gov/members/committeesDetail.asp?ID=3>.