

**OPTN/UNOS Operations and Safety Committee
Meeting Summary
January 26, 2016
Conference Call**

**Theresa Daly, Chair
David Marshman, Vice Chair**

Discussions of the full committee on January 26, 2016 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at <http://optn.transplant.hrsa.gov>.

Committee Projects

1. Standardize coding system for organ tracking (AKA Electronic Tracking and Transport Project or TransNet)

Public comment for the Operations and Safety Committee (OSC) proposal for mandatory use of TransNet on deceased donor labeling was released on January 25, 2016. The comment period runs through March 25, 2016. A schedule of regional meetings as well as the actual proposal and regional slide set was noted as available on the OSC Share Point site. Regional representatives have the option of attending training on either January 27th or February 1st.

Committee Projects Pending Implementation

2. Clarify requirements for blood type verification

The Committee received an update on progress of implementing ABO policy modifications approved in June 2015. It programming has begun on the project. The ABO implementation work group continues to meet monthly to develop tools, such as updated templates, to help the community understand and comply with the polices that will go into effect later this year when programming is complete. A webinar will held on March 23rd to discuss compliance.

Other Significant Items

3. Patient Safety Advisory Group

Members were urged to join the Patient Safety Advisory Group (PSAG) that meets monthly to produce educational products that share fictional events safety events and prevention strategies. The videos produced by UNOS staff in collaboration with the PSAG have been well received in the community.

4. Report on "Ethical Considerations of Imminent Death Donation"

Committee members reviewed a presentation on Imminent Death Donation with a focus on Live Donation Prior to Planned Withdrawal (LD-PPW). Prior to the meeting, members had received the report "Ethical Considerations of Imminent Death Donation" to review and develop comments. The Operations and Safety Committee had several representatives on a multi-committee effort led by the Ethics Committee to examine this issue. OSC has been asked to submit formal comments for consideration by the OPTN/UNOS Board of Directors.

Committee members discussed the topic. The following represents issues discussed and feedback to be formalized in a memo for the Ethics Committee:

- The OSC requests more data on the potential number of organs (single kidneys) that might be recovered through LD-PPW. It is imperative that the impact on Donation After Cardiac Death (DCD) be factored into these estimates. Because LD-PPW would require complex ethical discussions and major operational changes, the Committee strongly feels that the overall net impact on donation must be estimated prior to further significant efforts. One member stated that there are “many serious operational, ethical, and public perception issues to be tackled” and the member “urges thoughtful deliberation including data analysis on the actual potential”.
- Most OSC members did support further discussion and exploration based on the perception of the potential for many single kidney donors to be recovered for transplant. Those perceptions though varied and thus the previously noted need for data modeling is further exemplified.
- Committee members, in general, acknowledge that IDD may have a place in transplantation. Some donor families are willing to try anything in order to have a donation take place. There may be circumstances where a potential DCD is not projected to expire in time to donate and that LD-PPW might be an alternative in this type of situation. It was also noted by some that the predictive tools for DCD are somewhat limited and that the type and level of end of life care impacts these donations.
- Some members stated that they thought that families who reject DCD would not be more willing to consider LD-PPW
- Members discussed the need to define clearly the role for OPOs. OPOs do not take care of living donors. This would be a breach of federal regulations (e.g. Centers for Medicaid and Medicare Services) and a possible violation of the “dead donor rule” which speaks to the role of the transplant program in current living donor recovery. OPOs do not discuss DCD until the family has decided to withdraw care.
- Roles of both OPOs and transplants hospitals would need to be clearly defined as they relate to any participation in the recovery process. One member suggested that OPOs could help with policy/protocol development and assist with evaluation of suitability and perhaps family interactions; but OPOs should not be involved in the actual care of the living donor.
- The concept of whether an advocate similar to the current living donor advocate would be needed was raised. One member asked about the Advisory Committee on Organ Transplantation and their proposal 35 about living donor advocates. The surrogate could be viewed as an advocate to some degree however, you are going to have a living donation then return to the ICU and then withdraw care. The delineation of events would need further clarification.
- It was noted that due to the living donation aspect that LD-PPW would presumably have to take place at an OPTN member hospital. This issue was

identified as one introducing complexity into this potential type of donation. Because the potential donor may not be at a member hospital, the donor would have to be transferred to an OPTN member hospital. OPOs do sometimes have to transfer potential deceased donors to tertiary centers to access certain equipment. This can be a complex and costly undertaking and is done under the receiving hospital's physician authority. Transfers also incur medical risks and some transports have actually have negative impact on organ viability. These types of transfers have also been done in cases where a hospital does not allow DCD (e.g. Catholic hospitals). Some parallels could apply here.

- Requiring the LD-PPW to happen at an OPTN hospital also starts to blur the line between the transplant hospital and the donor hospital, which are definitions that the transplant community traditionally tries to keep separate.
- One member noted that having to transfer may be a burden on member families but also mentioned that it appears that families have been willing to accept this burden in some DCD cases.
- Members brought up that the cost issues involved with transfer would be significant and this concern would need to be addressed.
- It was noted that in some areas DCD took 10 years to become part of accepted practice and that was due to donor family insistence. LD-PPW may also face stiff opposition however if donor families desire this approach and strongly advocate this may move the public towards acceptance.
- The OSC asked if other respected bodies without a conflict of interest such as the Institute of Medicine (IOM) might weigh in these questions and the possible practice of IDD. Many of current industry DCD practices have been based on IOM recommendations. One member commented, "...that the renewal of DCD practice came with quite a political uproar. Following the IOM report was instrumental for our OPO to gain local buy in."
- One member stated that one of the concerns about IDD is that the broader non-transplant community already may be concerned about organ donation as they voice concerns that the hospital and doctors may withdraw care or not provide robust care in order to make a person an organ donor. This concern has been expressed especially in minorities. This new concept, LD-PPW, will only heighten these concerns. This member did not feel the report adequately addresses the ethical concerns or the possibility of erosion of trust and the outcomes of LD-PPW.
- It was noted that should this move forward a comprehensive education and public affairs outreach campaign would be required to address public perception concerns. All critical stakeholders should be engaged including possibly the IOM, professional medical groups, palliative care, patient advocacy groups, and faith groups. It will be critical to do all preparatory work up front to maintain integrity of system overall and avoid negative perception issues.
- OSC members reiterated that modeling of the potential net gain or loss of available organs must be performed before some of the other more complex

challenges are addressed. If modeling does not show potential for significantly increasing the number of organs available, it may not be worth further efforts since it will be a complex undertaking. The decision on whether to pursue this option needs to be informed by data.

Upcoming Meeting(s)

- February 23, 2016 (monthly teleconference call)