

**OPTN/UNOS Operations and Safety Committee  
Meeting Minutes  
June 1, 2017  
Conference Call**

**David Marshman, CPTC, BS, Chair  
Michael Marvin, MD, FACS, Vice Chair**

**Introduction**

The Operations and Safety Committee met via Citrix GoToTraining on 06/01/2017 to discuss the following agenda items:

1. TransNet<sup>SM</sup> OPO Packaging and Labeling Deceased Donor Organs
2. Ethics White Paper
3. IT Follow Up

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

**1. TransNet OPO Packaging and Labeling Deceased Donor Organs**

Committee members celebrated that mandatory TransNet OPO usage for packaging and labeling deceased donor organs (except vascularized composite allografts) went into effect today, June 1, 2017. The chair thanked all of the members and UNOS staff for the significant efforts to get TransNet to this level of use. The Committee will be monitoring usage going forward. For the first three months, UNOS will offer 24-7 help desk support and then will reevaluate the need for this level of support.

**2. Ethics White Paper**

Committee members were asked to review a white paper the Ethics Committee is preparing to send out for fall public comment on living donation among terminally ill donors. The paper addresses living organ donation by persons with certain fatal diseases who meet the criteria to be living organ donors. While Operations and Safety Committee members participated in a previous Imminent Death Donation work group, this effort is different. This paper focuses on those with a terminal illness who could provide first person consent to be a living donor. Since the new living donor consent went into effect in 2014, some transplant hospitals have interpreted that this type of donation might not be allowed under current policy. Some Ethics Committee members have been asked to consult on these types of cases. While some cases have occurred, hospitals are generally hesitant to proceed due to living donor death reporting requirements. This paper could provide some voluntary guidance in these situations.

Operations and Safety Committee members were asked to provide feedback and help answer the following:

- Did you identify any additional operational issues that should be addressed?
- Did you identify any additional safety issues that should be addressed?
- Would you recommend that the Operations and Safety Committee support this white paper?

It was noted that the Committee would have the opportunity to provide formal feedback during the public comment period but that it would be helpful for the Ethics Committee to attempt to identify any concerns this Committee might have prior to public comment.

Members reviewed the white paper recommendations that state that policies or protocols to facilitate this practice should be considered to avoid undue scrutiny or punishment for living

donor deaths that are required to be reported to the OPTN. The Ethics Committee would not develop an actual policy proposal. Any proposed policy changes would fall to other Committees, such as the Living Donor Committee. The Ethics Committee would recommend that centers not to be penalized if they are doing this to support the living donor in these situations. This is a position paper and the Ethics Committee is asking other Committees to consider these questions. The position paper starts the discussion and lays out the issues such as it presents a concern to report the eventual living donor death as it makes hospitals hesitant to do this type of donation.

Committee members discussed some questions that they had after reading the draft. Current OPTN Policy 18.6.A requires living donor deaths that occur within two years of the donation to be reported to the OPTN. the review process for living donor deaths that are reported through the Patient Safety Portal. Each reported living donor death that occurs within 2 years of donation is reviewed by the Membership and Professional Standards Committee (MPSC), as required by Policy 18.6.A.

(This policy states: "Recovery hospitals must report [when] a living donor dies within 2 years after organ donation to the Improving Safety Portal within 72 hours after the hospital becomes aware... The Membership and Professional Standards Committee will review all cases reported...and report to the OPTN Board of Directors.)

Members asked if the types of cases being discussed would be viewed the same as a living donor had died in a motorcycle accident. They indicated that these types of deaths would not generally warrant action as they did not contribute to the living donor death.

One member stated that this distinction could get a little slippery. The act of donating a kidney could actually add to the progression of the illness. One member stated as long as the act of donation does not necessarily hasten the death it would be acceptable. The living donor would need to have a good understanding of the living donation process.

Members noted that the definitions are somewhat confusing because the terms are so similar. Members asked about the timeline used to help define fatally ill versus terminally ill potential donors. Some members indicated that they were not sure the timeline is needed. The timeline could be confusing if you have an 80 year old that has a fatal illness with a 10 year expected death. Another member noted that the timeline is needed so that we are not just looking at people with chronic disease. Another stated that perhaps years should not be put on the timeline. Members inquired about the basis of the time frames and whether they were widely accepted in the palliative care community. The Ethics Committee liaison stated that he would follow up on this question as the answer was not cited in the paper. Members had different opinions about the need for the time frame with years but in general supported having some definitions. The Committee noted that this type of donation would not in general impact how things work operationally.

It was stated that this type of donation could be a great opportunity for people to give who are ill. It was also noted that it could bring up trust issues in certain communities. It could be seen as trying to get organs before people pass away and could be tricky in certain communities. It was also noted that the Minority Affairs Committee is also reviewing the paper. The question of the acceptability of who should bring up the organ donation topic was discussed. Someone who is terminally ill might not even know this is an opportunity. One member stated that just letting them know it is an option is not an undue pressure. Another noted that this is a tough area as doctors do not generally bring these topics up at other times (talking to you at your annual physical if you want to give a kidney). No other population has this as a routine conversation. Suggesting that this be part of a routine conversation could be perceived as seeking donors out and that would be questionable. It could be that the paper is silent on this issue or that a neutral

stance is taken and the discussion is neither suggested or prohibited. One member expressed that only the potential living donor should breach the subject. If medical personnel bring up the topic, then this might erode trust in donation for some in the public. Others felt that it might be appropriate for medical personnel to bring up the subject along with other topics that are discussed regarding death plans. One member shared that he had a family member with Lou Gehrig's disease and that organ donation was discussed in their support group. He stated that several in the support group wanted to donate their organs. They talked about where they could go and so it is not something that is hidden among some groups with known terminal illnesses. It was noted that the Ethics Committee would probably want to discuss this question as it had not yet come up in the development of the paper. The Ethics Committee will be asked to consider this question and perhaps add recommendations to the white paper.

The Committee did generally support the Ethics Committee sending the white paper out for public comment. They did not express any reservations that the paper should not be sent out and felt that it will generate relevant discussions.

### **3. IT Follow Up**

As requested previously by the Committee, the UNOS Customer Advocacy Director presented potential options for TransNet functionality. A wireframe that would place TransNet as an option in UNet<sup>SM</sup> was shown. It could be that TransNet would be the only application to be accessed for some users. The UNet site administrator would be able to manage the security options. Members were asked if this addressed the needs discussed at the last two meetings. Some members liked this proposed functionality. One member though asked about the option of not having a log in. The demonstrated option would require a log in. TransNet, however as currently being piloted for transplant hospitals does not require a log in. Health Insurance Portability and Accountability Act of 1996 (HIPAA) concerns were mentioned. One OSC member stated that it might not be reasonable to not have to a log in. One member stated that they could not see how you could do ABO verification without log in. It was explained that the recipient ID band and all data populated except for the patient name is based on the donor ID. They are able to see that it is the same people. It was explained that in the current pilot state, the information used is the same information that is on the outside on the organ label and does not give access to protected health information (PHI) It was noted that in order to access reports which do contain PHI, a log in is required. Committee members and staff discussed this issue that has arisen several times previously.

One member talked about the difficulties in managing OR staff access even if it were to be within UNet due to the number of staff members. For kidneys it would probably involve every single OR staff member so the permissions would be challenging. On the other hand if the functionality offered a uniform, consistent, and compliant manner to perform ABO verification then it could be worth the effort. It was noted that this might be the most difficult issue to work through. UNOS staff shared that the pilot was based on interviews and traveling around the country to transplant hospitals who indicated that having a log-on would decrease use and acceptance.

It was asked if the current pilot had been vetted and found acceptable by the Centers for Medicaid and Medicare Services (CMS). One member noted that CMS has had many questions upon audit regarding verification practices. UNOS staff had had a face to face meeting with CMS over a year ago. CMS did not express any concerns with the functionality that can generate a report. The report includes the ability to document an attestation of the scan and the verification. They were fine with the documentation being produced by TransNet. They gave the rubber stamp as long as members do things in the correct order and it aligns with the their policies and procedures. TransNet has the ability to time stamp all verification activities.

Scanning of barcodes lessens burdens than those with manual verifications. Armbands are printed out of match screen. Ninety-percent of the time coordinators perform functions off site but to accept an organ offer they must log in to DonorNet and then they can print armbands on a network printer. Some OSC members noted it would require some careful work to get onto a network printer. TransNet staff have been working closely with pilot hospitals and have had success in getting network print access so that pilot sites can start print functions from off site.

Operations and Safety Committee members were asked what TransNet transplant hospital mandatory use would entail. Members indicated that organ check-in and ABO verifications were key. The Committee did not see extending TransNet to organ re-packaging (deceased and living donors) at this time. It was asked if living donor organs that stay within same OR suite need to be packaged and labeled. OSC members replied that surgeons do not want to package living donor organs that will be going down the hall.

Current and future potential options for functionality were reviewed and shown according to the table and power point slide summaries below:

**Table 1: Proposed and Current Functionality**

Functionality	UNet <sup>SM</sup> Application	Deceased Donor	Living Donor
Organ Check In	TransNet <sup>SM</sup>	YES	YES
Pre-Recovery Verification	DonorNet <sup>®</sup>	YES	N/A
	TIEDI <sup>®</sup>		PROPOSED
Pre-Transplant Verification Prior to Organ Receipt	DonorNet	YES	N/A
	Waitlist <sup>SM</sup>		PROPOSED
Pre-Transplant Verification Upon Organ Receipt	TransNet	YES	PROPOSED

**Power Point slide summaries:**

Phase one functionality would be geared at transplant hospital functionality.

- Addition of Pre-recovery verification for living donors
  - Programming within TIEDI
  - Include ability to print organ label and recipient ID band
- Addition of Pre-transplant verification prior to organ arrival for living donor recipients
  - Programming within Waitlist
  - Include ability to print recipient ID band
- Pre-transplant verification upon organ arrival for living donors

- Programming within TransNet
- Using organ label printed from TIEDI
- Using recipient ID band printed in TIEDI or Waitlist

Phase two would target labeling and packaging of living donor organs.

- Ability to package and label living donor organs leaving recovery facility
- Build functionality within mobile app to allow OPOs to package and label
- Question: How would the user get access to donor info in Tiedi?
  - New security option within Secure Enterprise<sup>SM</sup>?
  - OPO would have access for all transplant hospitals in their DSA?

Members received an overview of the proposed functionality. The organ check in for living donors does now require manual entry of information since barcode and label printing is not within current functionality. The potential functionality being discussed would add similar functionality to TIEDI as exists in DonorNet now for deceased donors. Solutions would add functionality that could be used for living donors and their Waitlist recipients. The functionality would allow the ability to print verification forms without identifying information on either the living donor or recipient so that PHI would not be put into recipient medical record. The user would need to enter the intended recipient information and then a call back would go back to Waitlist to make sure the intended recipient is listed. It would then provide a pop up with donor and intended recipient information. Either identifiers (donor or intended recipient) could be blinded according to need. The goal is to also add an attestation statement to complete verification requirements. It would allow printing a TransNet organ label and recipient ID armband label so this could be included with the organ if it is being shipped. If it is in the same facility, then it could still be printed and sent with the organ in the same suite.

A mobile application could be programmed to allow OPOs to package and label living donor organs. Committee members were asked how would they recommend that OPOs access information within TIEDI. There would be a possible need for a new security group for those transplant hospitals to grant OPOs either individual rights or perhaps to grant access to all living donors within the donation service area (DSA). Committee members will consider this question and discuss at future meetings.

It was also shared that Epic has signed a non-disclosure agreement with UNOS as the two organizations work through potential mutual building of application program interfaces (APIs). UNOS staff continues conversations with several electronic medical records (EMR) vendors and held a meeting at the Transplant Management Forum in April 2017. A survey was sent out to all participants. Their responses will drive API prioritization which could include TransNet. Responses are due back in mid-June.

The Committee was supportive of what was shown and will devote its entire July meeting to continue this discussion. They were very encouraged with the proposed plan. UNOS staff will also obtain some more details on the IT side regarding timing and sizes for the Committee.

#### **4. Other Significant Items**

The chair thanked Committee members who will be rolling off on June 30<sup>th</sup> for their service.

#### **Upcoming Meeting**

- July 27, 2017