OPTN/UNOS Operations and Safety Committee
Meeting Summary
December 1, 2016
Conference Call

David Marshman, Chair
Dr. Michael Marvin, Vice Chair

Discussions of the full committee on December 1, 2016 are summarized below. All committee meeting summaries are available at https://optn.transplant.hrsa.gov.

Committee Projects

1. **Infectious Disease Verification Process to Enhance Patient Safety**

   ABO Post-Implementation Policy Modifications

   The Committee was updated on the status of the ABO post-implementation modifications approved at the November meeting to send for consideration by the OPTN/UNOS Board of Directors (BOD). The proposal will be on the consent agenda at the BOD meeting later this month (December 5-6). The Ad Hoc Policy Group unanimously recommended approving the proposal. The proposed policy language was amended to keep the laterality verification requirement for lungs at the pre-transplant verification prior to organ receipt when surgery starts prior to organ arrival due to safety and clinical implications. Committee leadership agreed with this amendment. Committee members did not express any concerns with this amendment.

   Current Infectious Disease Verification (IDV) Public Comment Proposal

   The Committee was given a quick review on the IDV proposal status. The Committee decided not to go to December BOD due to significant public comment. The Committee agreed that an IDV solution was still needed but that it must be a different solution than was sent out for fall 2016 public comment. It was also agreed that an IDV solution could not wait exclusively for an electronic solution as this may take several years. The Committee plans to pursue policy that requires individual organization review of results by two-persons. The goal is to address pre-recovery in the first half of 2017 and then move on to pre-transplant for fall 2017 public comment.

   The IDV work group is working on revised recommendations. This group includes representatives from other Committees including the Transplant Administrators, Transplant Coordinators, Living Donor, and Organ Procurement Organization (OPO) Committees. They have been meeting and discussing development of a policy concept that would allow flexibility in performing an infectious disease verification but still have required pre-recovery steps (prior to the ability to implement an electronic solution).

   The work group last met on 11/30/2016. They had a discussion over words used to define and describe timing of the verification. The desired concept is flexibility to allow the verification to occur anytime the results are back (within testing policy requirements) but prior to organ recovery.

   There was discussion on responsibilities of donor recovery versus transplant hospitals. There was debate over the responsibility of the donor recovery hospital. The group debated questions around whether this responsibility is just for donor safety or is there any responsibility to confirm that results are acceptable for recipient. The work group

was divided on this potential responsibility on the recovery side. All work group members agree that the transplant hospital still has responsibility for assuring that results are acceptable for recipients.

Current policy responsibilities for both OPOs and living donor recovery hospitals include those for the HOPE Act (both living and deceased must have certain verifications including that the intended recipients willing to accept an HIV positive organ) and for ABO (must verify correct donor/intended recipient and compatibility status).

Once the work group discussions were summarized, one member shared how they have changed their opinion on the donor hospital responsibility. It was explained that the donor hospital should verify that the recipient would accept the results because without this it would be possible to have a recovery and surgery go nowhere. It could be a simple documentation that yes, we have reviewed the results, and we are accepting the organ with those results. Another member voiced support and stated that the recovering hospital must have some part in the verification because they are doing the surgery and need to know that the recipient will accept the results in order to avoid unnecessary surgery. Eventually a poll was launched so that all opinions could be considered. The poll asked: "Should donor hospitals have any infectious disease verification responsibility for positive results?" Nine (9) members voted yes and one (1) member abstained from the question.

The idea was debated if it matters whether the recovery and transplant facilities are the same. Members had varying opinions on this subject. Some pointed out that although it is the same facility it could be very segregated programs. Another offered if both a recovery and a transplant pre-verification were being done by two people then why would you need to document communication between the two programs. Another person pointed out that the transplant team might have missed a result and that is why the communication between facilities is needed. Another member explained that if both the donor and recipient teams are the same or they both participate in a selection process that the verification and confirmation that the recipient will accept a "positive" organ could take place at the same time. A member commented that a case had transpired where the donor and recipient teams were at the same institution.

The Committee was also asked if anything about the donor results need to be acceptable to recovery hospital protocol (e.g. –HIV and HOPE Act). It was decided that this was not necessary, as it was perceived to be overkill. It would be getting away from the project intent and outside of what this verification is intended to solve.

Some other possible donor hospital responsibilities were discussed. These included the following draft clauses:

1. Inform the donor prior to the recovery

2. Exclude living donors according to Policy 14.4.D Living Donor Exclusion Criteria

   (HIV positive only under HOPE Act and Living Liver donors are excluded for HCV RNA positive or HBsAg positive)

3. Manage positive HIV results according to Policy 15.7.B Requirements for Allocating HIV Positive Living Donor Organs if recovery will proceed

   (15.7.B: In addition to the requirements of the OPTN Final Rule, the recovery hospital must confirm that the potential living donor is HIV positive and the potential recipient is willing to accept an HIV positive organ as part of a research protocol.)

4. Report results to the recipient center within 24 hours of receipt if recovery will proceed

5. Confirm that potential recipient is willing to accept an organ with the positive result

It was noted that numbers two and three may be redundant and not needed in policy but are listed to help the Committee frame discussions with knowledge of current policies. The Committee debated the fourth and fifth clauses. It was noted that test results may be ordered on 20 potential living donors at a time and may not be reviewed for several days. One person did talk about the need to know positive results quickly in the context of kidney paired donation (KPD) and how they would want an immediate call on a positive result.

It was explained that some timeframe is needed. With vessels policy, half of transplant programs did not report due to the lack of time frame. It was noted that you can schedule 4-5 months in advance and then results could change. The Committee robustly discussed and ultimately disagreed with a 24-hour turn around. The Committee agreed that the timing could be prior to organ recovery. It would not be needed to impose an unrealistic requirement, but the time proposed (prior to organ recovery) would be sufficient to ensure living donor safety (avoid unnecessary surgery) and recipient safety (avoid accidental infectious disease transmission).

One member indicated that number five might supersede number four or the two could be combined. The Committee will be sent an email to gather more feedback about their opinions on these options.

2. **Standardize an organ coding system for tracking of organs (TransNet^{sm})**

Committee members were provided a brief update of the status of TransNet and transplant hospital functionality. They were also provided an overview of two types of information technology (IT) pathways and the scope of each. The most familiar and traditional pathway is the OPTN project pathway where projects are approved for Committee work by the Policy Oversight Committee (POC). If there are new data requirements, then the project must go out for public comment. Following public comment, the Committee then chooses whether to submit the proposal to the OPTN/UNOS BOD for consideration. If the project is approved by the OPTN/UNOS BOD, then it is prioritized within the scope of all approved OPTN IT projects.

The Committee identified developing TransNet functionality for transplant hospitals as a high priority at their in-person meeting and referred this back to the TransNet Work Group. This group recommends completion of deceased donor functionality as the number one priority. The group will continue to meet and develop projects for additional TransNet functionality (e.g. vessels, infectious disease, and living donor). Of note, these types of functionalities would require web-based programming and not be dependent on the more limited resource of mobile developers.

The Committee also heard about a newer process for IT projects to be developed and implemented. The UNOS Customer Council pathway is a pathway for IT enhancements only. This pathway is not for projects that have new member requirements. Enhancement ideas are received from members and Customer Council (CC) members. The CC is an ad-hoc group of OPTN members. Ideas submitted are validated by CC. Ideas are prioritized by UNOS internal IT and business staff, as well as the external CC members. The ideas are then scheduled within the scope of all IT work, which includes other types such of projects such as browser upgrades and technical debt.

UNOS IT leadership also discussed plans and development of application programming interfaces (APIs). UNOS IT has started developing APIs in several areas. There are several goals for APIs. These include reducing data burden, improving data quality, improving security, expediting data sharing, and focusing on patient care. A review was given of APIs currently in progress such as those for DNR, attachments, and CPRA calculations. The possibility of building APIs for TransNet was discussed. Currently, transplant hospital TransNet beta testers must use the TransNet website to scan the shipping label, enter location information, and document the organ check-in. There are 13 facilities currently testing. They have performed over 500 organ matches and 1000 organ check-ins. An additional 25 transplant hospitals are in discussions. One of the identified drawbacks can be that TransNet does not interface with transplant hospital EMRs. With an API, an "information bridge" would be built. Transplant hospitals could use an API to access TransNet through their EMRs. Documentation could be in both the TransNet and EMR systems.

How this type of API would work was explained to the Committee. When the barcode is scanned in EMR, then the API makes a call back to TransNet. It unencrypts the barcode and provides donor information to EMR. It pulls information regarding the check in or match back to TransNet. The benefits would be that users would only have to access one system (EMR). The data would exist in the EMR as well as the TransNet system (without additional manual steps). APIs would be available to all EMR vendors who wish to program to them. Members without EMRs (or EMRs that do not program to APIs) would still be able to perform all functionality from TransNet website. API functionality would require both UNOS and EMR vendors to build their half of the bridge to facilitate this type of information exchange. The goal is to create parallel ability to implement more features. Smaller segments (projects) are easier for IT to develop and implement. All IT teams are also getting more mobile development experience. It was noted there is not any more dedicated funds from HRSA for TransNet development so that it must be worked in across the board of all projects.

One member asked and it was noted that iTransplant would be included in the API development. Committee members were urged to express to their EMR vendors that transplant APIs (including TransNet) were a need and priority. UNOS has started discussions with EPIC due to transplant member requests. EPIC has indicated some interest to start working on transplant APIs in mid to late 2017. The UNOS portion would be open to all EMRs. One Committee member noted that there is no doubt that APIs would increase safety and efficiency but asked how we can help the hospitals to see the value and convince them to pay for this. UNOS IT leadership noted some of the benefits and that EMRs have stated it could save money. It can save costs because the need to maintain UNOS-specific forms could be eliminated. Costs can also be saved through reduced auditing expenses and increased data quality. APIs increase the ability to transmit data accurately and there should be fewer mistakes with APIs.

One member asked for more evidence to take back to their institution. It was noted that we do have data and that we do have OPO testimonials. One member suggested developing a poster or break out session at professional meetings to promote the benefits using these data. Another member volunteered that they were a beta site for TransNet. They are using it for organ check in and explained that although there have been bumps in the road, it is useful, and improving as more organs have barcode on them.

In learning about the pros and cons of transplant hospital and TransNet use, staff offered that the pros are the multiple data points captured that can support documentation such

as when the organ arrives at the facility or on the operating room. These times have been difficult to document and have evidence. Referencing TransNet reduces risks and gaps from the compliance stand. It was noted that the check-in is to the facility (not recipient) and that this part is very helpful.

Upcoming Meetings

- January 5, 2017 (Monthly Conference Call)