

**OPTN/UNOS Operations and Safety Committee
Meeting Summary
October 25, 2016
Chicago, IL**

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

Discussions of the full committee on October 25, 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

The Committee reviewed public comment from their recent proposal to add requirements for infectious disease verification (IDV). Significant public comment was received on this proposal. The proposal was defeated in eight regions and approved in three regions (one region approved with an amendment to allow verifications to take place in alternate areas). The proposal was presented to ten other OPTN/UNOS Committees. Positive feedback from Committees was received in support of the concept however many had heard and agreed with community feedback that the logistics in the proposal were problematic. The American Society for Transplantation (AST) and American Society of Transplant Surgeons (ASTS) opposed the proposal. NATCO expressed concerns, while the Association of Organ Procurement Organizations (AOPO) supported the proposal.

Major themes identified and discussed by the community included:

- Do not believe risk/benefit supports solution proposed
After reviewing public comment and after debating various considerations such as possibly having different processes for deceased and living donors; revisiting the logistics of the proposed solution; and still reaffirming the need for some type of infectious disease verification, the Committee agreed that the proposal and its solution need to be reworked.
- Logistics: Area of verification (OR, Pre-OR)/Timing of verification/Who performs verification/ OR staff hard to train
The Committee sought specific public comment on the proposed area of the verification. ABO and infectious disease verification were combined in the proposal, necessitating tasks be done in the OR. The Committee asked for comment about using the pre-operative holding area and potential definitions to provide more flexibility. What the Committee heard in public comment was that the logistics of the proposed solution would be too difficult to enact. This discussion went beyond just the place of verification. The Committee decided to combine area, timing, and persons performing verification into one category which refers to the logistics. While there were those supporting the concept, the logistics as proposed were strongly opposed by the community. The Committee discussed that while the idea of combining this verification with ABO seemed logical and reasonable that it created concerns. About 80% of deceased donor cases will have all results available at organ acceptance and these could be handled differently. The Committee recognized issues with programs without dedicated OR staff and the complexities in verifying infectious disease results

(e.g. HCV antibody positive, NAT negative). It was noted that public comment and ultimately the Committee agreed that the proposal might be too much burden on staff who are not qualified to verify testing results and implications. The Committee discussed that living donor infectious disease verification could probably happen at a time determined by the program within the 28-day window when testing must be completed prior to surgery as long as all results were available and reviewed. Staff shared there is a Member Quality (MQ) report run nightly to identify and follow up on discordant UNetSM data when the candidate was not willing to accept a positive organ on screening criteria but the test results were positive.

In discussions with the Transplant Administrators (TAC) and Transplant Coordinators Committees (TCC), the request was to move IDV up earlier in the process. The complaints of verification fatigue and risks of checking a box off in the heat of the OR just to say it was done were valid concerns recognized by the Committee. Documenting verification can be intensive.

The Committee struggled with how to move back timing for deceased donors yet have effective communication and verification for those that have pending results at organ shipment or transplant. Several on the Committee opined that they thought these numbers were small but it was acknowledged that the closest data point available for analysis was organ acceptance. Recognizing pending results and completing follow up on them was viewed as crucial for IDV. This is where a gap exists that could lead to unwanted outcomes. When results are positive, who is communicating, and how are they communicated to the transplant hospital were identified as important areas to plug holes where errors can happen.

The Committee agreed too that they should evaluate area of verification as well as all logistics to become less scripted for transplant hospital processes.

- Technological solution needed (e.g. TransNetSM/Mobile DonorNet[®])
Many transplant community members asked for electronic solutions, specifically TransNet, to be fast-tracked. The Committee agreed that having an electronic solution would greatly support infectious disease verification. However, the Committee realizes that full TransNet functionality and mandatory use is likely years away. The Committee ultimately agreed that a stop-gap solution is needed prior to a full electronic solution as 6-7% of donors have positive results for HCV, HBV, or HIV. Increases are expected due to the HOPE Act and use of HCV positive organs in HCV negative recipients as new treatments are available. The Committee reiterated that one serious adverse event could have a significant negative impact on all of donation and transplantation.

The Committee also noted considering possible DonorNet solutions such as some type of an acknowledgement. For example, the Committee asked does DonorNet need to send a flag on positive results? It was also asked if there is, or needs to be a policy that DonorNet has to be reviewed? It was noted that something could be put in at organ acceptance.

- Too much complexity on top of ABO
The Committee recognized the significant comment on this point and ultimately agreed the current proposal is not tenable. The Committee agreed to go back to the drawing board with the goal of increasing flexibility and finding a more acceptable process. The challenges of a one-size fits all solution were noted as volume often drives widely varying practices.
- Support for IDV Concept
The Committee discussed that many in the community did express support for the general concept. The Committee reviewed the events that led to the Membership and Professional Standards Committee (MPSC)/Health Resources and Services Administration (HRSA) referral and endorsement by the HOPE Act work group for an IDV. Additional events, as well as unreported near misses, occurring in the past due to lab and other human error issues were mentioned.

Some members offered that negative results could be handled differently. Others pointed out that verbal communication should not be relied upon and to know results are negative someone must review them. This makes it difficult to develop policy for “positive” results only. It was asked if it was a safe practice to have a surgeon read results. Many noted that verbal communication might not be sufficient. It is not the best idea to assume a result is negative, if an OPO does state positive results at organ offer. This can lead to error, accidental omission, or lack of follow-up on pending results. The re-execute the match run policy does address required process when results change to positive.

- ID Data Entry: Require double verification by OPOs
The Committee had a robust debate on how much of IDV could be handled at upstream points with the donor. Some Committee members stated this IDV responsibility was solely on the donor side. It was noted that while correct data entry is important it is necessary to have a transplant hospital responsibility for result review and determination of donor suitability.

Committee members felt that many OPOs were currently conducting double verification and that this concept could help prevent downstream errors. Double verification on the front end might eliminate some verification on the back end. To state that one does a practice “all the time” but not have it in policy is not sufficient and might be offered as a legal defense that does not stand up. On the donor side, it makes sense for double verification and for the recipient side, we must know that you looked at results. Although double verification by OPOs was not in the current proposal, the Committee will likely include this in the future.

- Standardize (revise) OPO reporting processes
It was noted the post-transplant results communication pilot could help with process. Labs, however, use varying terminology to report results and this group has no authority to change that aspect.
- CMV requirements
The Committee discussed the proposed inclusion of CMV for intestine recipients due to current candidate screening policy. It was noted although this concept was important 20 years ago it may not be clinically relevant now due to changes in

management of immunosuppression. It was agreed to refer this question to the Liver and Intestines Committee and potentially the Ad Hoc Disease Transmission Committee (DTAC).

- Undermines existing informed consent

The Committee debated this issue brought up in public comment. One member stated that you do not need to verify that a recipient is willing to accept negative results, yet it was also stated that the transplant hospital should have some recognition of reviewing negative results and documenting this review. It was suggested though that TransNet or DonorNet could be used versus source documentation.

One member mentioned that any data element could be required to be verified. The group ultimately agreed that infectious diseases needed policy. The critical thinking process might need to be documented.

The Committee discussed that maybe there could be a tiered approach: an acknowledgement of negative results and a different or an additional step for positive results. The Committee agreed that it is reasonable to expect that the recipient surgeon review results. Current policy does place the burden on transplant side to make sure recipient understands what they are getting. The Committee will consider if there needs to be second acceptance of positive results. The Committee did acknowledge that existing policy addresses consent, but that IDV is a necessary redundancy and represents the first step of consent because it is necessary to know what you are getting. Policy does address the need to consent for positive organs but that IDV does not undermine that policy.

Based on public comment and Committee discussions, the Committee has decided not to move the proposal forward to the OPTN/UNOS December Board of Directors (BOD) meeting at this time, but to rework possible solutions. The Committee reached consensus that there is a risk and some type of solution, prior to complete electronic verification, is needed. The proposal will go back to the IDV subcommittee to develop at least a partial proposal for the next public comment cycle. Shylah Haldeman will continue to chair the group. Living donor representation has been requested from that Committee but Operations and Safety Committee members with living donor experience were asked to join the group also. Upcoming public comment deadlines (January 2, 2017 and June 30, 2017) were shared to guide timelines.

Committee Projects Pending Implementation

2. TransNet for OPOs

The Committee received an update on OPO progress towards the mandatory June 1, 2017 implementation date.

TransNet versions 5.3 and 5.4 have been released. Functionality added includes:

- Phase 1 Label Verification (released 7/25)
- Single user access to multiple facilities (release 10/26)

Version 6.0 is in progress and when complete will include:

- Package/label with multiple organs label (March 2017)
- Package/label VCA organs (March 2017)
- Package/label import organs (March 2017)

Other non-programming efforts include

- Creation of training plan for new functionality
- Standardization of TransNet help documentation (similar to UNet Help Docs)
- Transition of first level support from TransNet team to UNet Service Desk

OPO usage data was reviewed. These data do not include OPOs trained in September. The percentage of TransNet cases and the percentage using TransNet to ship at least one organ will be tracked. Data collection starts for each OPO on the first of the month after completing training. Previous data had not accounted for rolling start dates in the denominator (donors recovered).

In September 2016, 80% of trained OPOs used TransNet to create a case and 72% used TransNet to ship at least one organ. For those trained in the first cohort, usage rates at 92%. It was noted that 49 OPOs have been trained to date (including those trained in September 2016).

It was noted that Operations and Safety would use this data to monitor usage once mandatory use goes into effect on June 1, 2017. An evaluation group will look at data and review non-usage in a fair and just way as there can be technology or user failure. Monitoring will start three months after policy implementation and continue quarterly for the first two years. If there are usage issues, Operations and Safety will reach out to individual OPOs for troubleshooting before referring.

Implemented Committee Projects

3. ABO Implementation

The Committee has received post-implementation suggestions since the policies modifying ABO determination, reporting, and verification went into effect in June 2016. Suggestions have come in through multiple channels such as TAC and TCC meetings, written correspondence, and UNOS departments (e.g. regional administration, site survey).

The Committee will send a proposal for consideration at the December 2016 OPTN/UNOS Board of Directors meeting that contains some style edits from the fall 2016 infectious disease verification proposal along with some ABO suggestions received.

These proposed changes include:

- Revise and clarify use of identification band and OPTN computer system for “Donor ID”
- Review laterality due to difficulties in finding and using acceptable sources
- Add “surgeon attestation” as acceptable source for living donor correct organ/correct intended recipient
- Add OPTN Computer System as acceptable source for recipient blood type (pre-transplant verifications) since organ verification link (OVL) is now available.
- Change acceptable source term as this gets confused with “source document”

- Make tables 508 Compliant and name verifiers in table versus list format (In IDV proposal)
- Incorporate organ tracking system as acceptable source (in IDV proposal)
- Incorporate other policy edits (In IDV proposal)

The Committee agreed with these concepts. The Committee will discuss and vote on proposed policy language changes at their next teleconference meeting on November 3, 2016.

Two requested items are to develop OVLs (available for deceased donors) for living donors and Kidney Paired Donation (KPD). This would require programming. An internal group is looking at high-level concept and potential requirements to recommend a path forward. Living donors do not have a match ID so it is more complicated. The group was asked to reflect if they had to enter three or four data elements for the system to pull the correct living donor and candidate, then would the OVL still be useful.

Other Significant Items

4. TransNet for Transplant Hospitals

An update was given on transplant hospital TransNet development and use. Thirteen facilities are using TransNet. There have been roughly 500 organ matches (pre-transplant verification when the organ is present in the OR) performed and 1,000 organ checked-ins performed. An additional 25 transplant hospitals are in various stages of planning to use TransNet.

Several barriers to getting transplant hospitals up and running were discussed:

- Limited to post organ arrival match for deceased donors only
- No interface with EMRs
- Discussions are in the early stages
- Multiple competing priorities
- Requires buy-in from: transplant coordinators/surgeons, OR nursing, IT security, compliance/regulatory, leadership

The only functionality left to be programmed is the pre-transplant verification when surgery starts prior to organ receipt in the OR. This will be programmed sometime in 2017. Other potential projects include:

- Completion of transplant center functionality for deceased donors/infectious disease verification
- Living donor functionality
- Vessels
- API integration with EMRs (currently in discussion)
- Infectious disease verification in pre-transplant verification (based on future policy)

The benefits of focusing on deceased donor functionality would be consistency for all deceased donor transplants and highest impact based on volume. The drawback is that it does not address having a separate process for living donor transplants.

Functionality for a living donor organ check-in has been added. It requires manually typing in the data. One member is currently participating and noted that they often have to type in data for check-in and until OPO use becomes mandatory that will probably be the case. Considerations for living donor organ check-in functionality are complex due to

the different processes used by recovery hospitals when packaging and labeling living donor organs. Considerations are:

- Who would package
- Organs that remain in the same OR suite
- Post organ arrival match
- Requirements
- Organs must have a TransNet generated organ label (with barcode)
- Must be able to print a recipient ID band
- Enhancing the pre-organ arrival verification for living donors (Policy 5.8.A)
- Pre-recovery verification (Policy 14.7) as there is no match ID

The benefit of living donor functionality would be a consistent process for all transplants. Other considerations include the education of individuals who would package/label; transplant centers may need to purchase additional equipment; and based on current living donor registration process, infectious disease verification would not work.

Another functionality requested by some in the transplant community relates to vessels. TransNet could provide the ability to scan the vessel label to document receipt, document disposition, perform match with vessel recipient, and integrate the scan to populate Tiedi vessels reporting form. The benefits would be:

- Warn/stop user from storing unacceptable vessel
- Send warning text/email when vessels about to expire
- Create catalog of vessels available for users facility
- Electronic sharing/tracking

One consideration is that the user would have to be authenticated.

It was noted that any additional transplant hospital functionality would need to go through the committee project pathway either as a part of a policy proposal or programming project. Only non-policy driven enhancements could go through the UNOS customer council (CC) pathway. Any enhancement can go through that direction. It was noted that BOD projects get top priority. Enhancements are put into backlog along with other technical debt and security items. These are prioritized by an internal group and the CC helps with this task.

Members were given a quick overview about how the CC started in late 2014. There are 15 community members (representing both OPOs and transplant hospitals as well as front line and management). The CC meets every other month. They receive enhancement requests (no policy implications) and review the request list to ensure relevancy. No enhancement is based on one request. This group reviews mock ups and enhancement ideas as well as generates ideas.

The project on post-transplant communications is one CC project. Once the pilot is complete however, it would need to become a committee project and eventually be approved by the BOD before programming would be completed. A brief history of TransNet funding was discussed to give new members perspective. Operations and Safety ended up with the project after specific carve out funding from HRSA ended in 2013.

There are not allocated resources currently to complete all that the community desires. It was suggested to focus on deceased donor functionality because transplant hospitals currently have two different processes between living and deceased donors.

TransNet staff shared that some members are resistant to use TransNet because it does not integrate with EMRs. UNOS staff are having discussions with EMR vendors. Some Committee members voiced that integration is not necessary if the verification can be printed and then scanned into the EMR. It was also shared that if TransNet can have the total ABO verification functionality that would eliminate many concerns. Infectious disease verification would be an easier sell if TransNet functionality existed.

Leadership expressed concern that community feedback might divert efforts. If the Committee is the one charged with prioritizing items, then the Committee needs to be the one doing that prioritization and their recommendations followed.

TransNet could be used for KPD but that is a bigger issue than just IT programming because of who packages and labels organs. The ideal of having a match for all living donors was mentioned. OPOs can be granted permission to run a living donor match but it is usually for non-directed donation. One member asked what would be easier, program TransNet living donors, or a UNet match run for living donors. It was noted that perhaps something less than a match might be used.

From the hospital IT perspective, there may be more pushback without an interface. When use is not voluntary but required, then that makes it easier to talk within hospitals. Transplant hospitals will not embrace TransNet without greater functionality and benefits. One member expressed that the Committee should advocate very strongly for getting there as soon as possible.

High-level estimates were requested. Tentative estimates for vessels and pre-transplant verification prior to organ receipt in the OR were estimated at 3-4 months each for a team of four programmers and two testers. Infectious disease verification is an unknown at this time. Living donor programming would likely take a year. UNOS staff were asked what this equals roughly in hours, which would be 4,500 hours at a very high-level estimate with technical debt included. The education for transplant hospital packaging and labeling is not included in these figures but would be significant.

Members estimated ballpark costs to be a half to one million dollars. One member stated that this is not a scary number if it was spread across all centers in the country especially when considering individual costs to train staff or program individual EMRs.

The Committee talked about next steps knowing there will not be more programming under the CC. Should the Committee ask the BOD to authorize all of the funding. Committee members felt not to finish the product on the transplant hospital side would be a waste especially in the context of the efforts and funding that have gone into the product at this point. One member said why develop the computer but do not include the internet. It was noted that everyone wants to see TransNet grow, but the Committee must choose priorities. One member asked that ten percent of the allocation UNOS received a few years ago (with an IT cost increase) be allocated to this project. It's possible some work could be done on Donor Net, and then perhaps TransNet could be its application. If the verification is done in UNet, then TransNet can just match. UNet could be the source document suggested one member.

It was noted that it was cumbersome to go from TransNet to EMR to do other verifications. The Committee stressed that TransNet needs full functionality. The issue will be referred back to the TransNet work group for further discussion, project development, and next steps.

5. Pilot to Use DonorNet to Report Post-Transplant Results

Members received a progress update from Amy Putnam, UNOS Customer Council Director, on a pilot information technology (IT) project that will allow OPOs to notify transplant hospitals of updated test reports through DonorNet®. The pilot is being led by the UNOS IT Customer Council. Preliminary work was completed during a SONU day with the assistance of a former Ad Hoc Disease Transmission Advisory Committee (DTAC) member, Chris Curran who is with New England Organ Bank. The pilot programming will be completed sometime in 2017. This will be done in a manner that is similar to how organ offers are currently communicated. Patient safety contacts (on call) using the current on call contact management system would be selected or indicated and OPOs would then choose the test type results that are available for view in DonorNet. Following the pilot and evaluation, the project would then be ready for Committee sponsorship.

The pilot is designed to be a proof of concept to help ease communication and acknowledgement of results received post-transplant. The current prototype was shown. The demonstration showed a notify button used by the OPO that calls back to waitlist for all recipients transplanted from a specific donor. The OPO can then choose which transplant hospitals by organ groups to notify. OPOs can enter any free text (max 500 characters). The transplant hospital will receive the same type of notification that they have chosen to receive for organ offers. A log of notifications sent, received, and method is kept. A more detailed audit log is planned for the future with date/time stamps for points of communication marked by user log on.

It was noted that they are also working with the DTAC and TAC. They have also spoken to a number of OPO groups who have had positive reactions.

It was requested that the transplant hospital be able to list more than one name. In the future, it could be that the system also notifies those persons on call. It was requested that a link to the recipient or match ID be included for ease of research. Another suggestion was to build the system so that OPOs can track what is pending. It was shared that some OPOs track within their systems and then execute within DonorNet. It was noted that UNet has similar functionality for pending verifications and that this could be a great feature to build pending results into a dashboard. UNOS IT is working on a prototype. The need to track if the transplant hospital has actually received and reviewed the results was seen as important by the Committee. A way to prioritize results and make notifications specific to organ according to policy was another identified need.

The Committee recognizes the need and fully supports the project. They offered any assistance needed. It is viewed as an efficiency project by Committee leadership due to the time currently spent researching and reporting culture results. It is possible that the Committee will be called on to provide more feedback in the future and help identify possible pilot sites.

6. Patient Safety Data Review

The Committee received a presentation from UNOS staff research analyst, Read Urban, and senior safety analyst, Kate Breitbeil, about changes to how safety data is analyzed and current data. The presentation aimed to:

- Help the committee understand what is reported
- Identify gaps
- Address high frequency/impact events
- Increase awareness
- Foster reporting
- Guide refinement to data analysis

Goals are to overall develop and implement a system for review of de-identified adverse events or near misses reported to the OPTN to identify potential network improvements and policy revisions necessary to prevent future occurrences; and to explore ways to disseminate information to the transplant community regarding outcomes of reported adverse events or near misses in an effort to heighten awareness of safety within the transplant community.

After reviewing categorizations provided via the Improving Patient Safety Portal (IPS) programming enhancements implemented on May 29, 2014, UNOS OSC support staff recognized that front-end categorization provided by members can be inaccurate and incomplete. Member front-end categorizations were based upon limited or minimal information regarding the actual course of events, root causes of the reported issues, and ultimate outcomes of the incidents.

To provide more accurate representation of reported OPTN-related patient safety issues, MQ determined that a post-case review would provide more robust and comprehensive classifications and outcome determinations. Patient safety reports received that warranted an investigation became a unique “case”. Duplicate reports were typically combined into one case. After a thorough investigation has occurred, some cases were later determined to be non-issues or issues reported in error.

During the investigation, staff would obtain pertinent information from all of the members involved in the reported patient safety issue. At the conclusion of each investigation, staff used a team approach to perform a back-end categorization of each case. This team review approach applied a consistent set of rules to determine the categories and subcategories assigned to each case and allowed for continuity and accuracy of data for analysis. There was a 32% discrepancy between the member front end and MQ back end categorizations. A mini data dictionary was created to help provide consistency to the multi-disciplinary team that meets weekly to review and categorize cases. It was suggested that the data dictionary be published on the IPS site to help members with their classifications.

Additionally, each case was reviewed to determine if the event resulted in the addition of cold ischemic time to an organ, non-recovery of an organ, or the discard of an organ. Member self-reporting on this is not always accurate and not part of events coming in through other channels. All cases investigated from all modes of receipt, including routine research reports such as Waitlist ABO listing discrepancies and prohibited vessel storage, were classified using this process. This process will streamline and provide more accurate and meaningful data for future analysis.

It was asked if feedback on classifications is shared with members and noted that this might not be appropriate, as all data are not self-reported. It was also noted that DTAC classifications are not shared back with members who report based on legal concerns to protect the peer review process. It was suggested that the findings and new process be submitted as a manuscript to the American Journal of Transplantation (AJT).

Data were shown on 167 cases. Of these, 91 were about a transplant program issue and 64 were about an OPO issue. Some DTAC cases also end up as a safety situation in cases where there was late reporting or other concerns for safety. The analysis represents all cases evaluated by the UNOS safety incident handling team.

Since patient safety cases may involve more than one high-level category, total percentages can exceed 100%. Overall, 24.7% of cases involved transplant procedure/process, 11.2% of cases involved testing, while living donor adverse event issues were also commonly reported (9.6%). The top three high-level categories were reviewed. Of the 42 transplant procedure cases, 30 (71.4%) cases involved prohibited vessel storage while 11 (26.2%) cases involved vessel sharing. Testing involves some one offs and more data will be needed to discuss potential patterns.

The group was shown the distribution of patient safety cases that caused or contributed to the non-recovery, discard, or delay/added cold ischemic time of any organ(s) between January 1, 2016 - June 30, 2016. Twenty cases were excluded from analysis of the non-recovery, discard, and delay/added cold ischemic time). Of the remaining 147 cases, 10 resulted in non-recovery, 9 resulted in the discard of an organ(s), and 11 resulted in the delay/added cold ischemic time. Among living donor adverse events, 9 out of 10 represent aborted procedures (these were required to be reported starting in 10/2015). Of the aborted procedures, five were recipient and four were donor based. Packaging and shipping was the most common category among the organ discard and increased cold ischemic time (CIT) cases. It was clarified that cases are in one of three but not in more than one category.

The group questioned three living donor deaths in the past six months. It was explained that these include any time frame reported and any cause of death. One member noted that she requests a data report limited to the past six months for data required to share with potential living donors. It was also noted that the MPSC must review every death regardless of time or reason. There is a formal attribution by MPSC and more data was requested to put these numbers in context.

Since these data have been analyzed differently, previous data will not be compared to data using the new process. Some potential enhancements to data collection were discussed including identifying self-reports and including whether living donor aborted procedures are recipient or donor based.

Potential enhancements to the next report include the following:

- Deeper dive into events leading to increased CIT, non-recovery, and discard
- Summarize investigation outcomes (i.e. how many were closed, referrals)
- Remove “noise” or non-patient safety related events
- Will be exploring harm taxonomy; cause and effect in partnership with HPI (Healthcare Performance Improvement)

The Patient Safety Advisory Group (PSAG) has decided to proceed with extra vessels as their next project. This is from an earlier Membership and Professional Standards Committee (MPSC) referral and supported by the most recent patient safety data. The aim is for a February product. It was requested that MQ aggregate root cause and corrective action plan data from these events. The safety incident handling team has done this for 40 reports. The summary is with the MPSC meeting concurrently. It is hoped they will approve and then the finding can be shared at the next PSAG meeting.

The Committee greeted this new project with a round of applause. It was noted that this is an enormous leap to share back to the community with transparency while preserving confidentiality. The importance and now possible actualization of a just culture was lauded. It was noted that current reporting only represents about 13% of probable events that have happened. With this type of culture hopefully reporting will go up as lessons learned are shared. The Committee applauded this direction and the work that has gone into getting reporting and analysis to this level.

Dr Michael Green spoke about the PSAG whose purpose is to use data to educate the community and inform policy if needed. While awaiting more back end data, the PSAG has embarked on a community education series with the help of UNOS Instructional Innovations. Quarterly 10-15 minute video vignettes have been developed to illustrate issues, contemplate solutions, and highlight potential best practices.

These started in October 2015. Kimberly Taylor, curriculum development instructor, reviewed the ones completed to date:

1. Proactively avert errors (two scenarios: disease transmission and switched laterality): 608 total views
2. Organ discards (two scenarios: one liver and one kidney): 438 views.
3. Hemodilution: 247 views
4. ABO verification (done as part of implementation): Over 2,300 views.
5. Allocation deviations (released August 2016) : 81 views
6. ABO subtyping interactive course developed following site surveyor identification and reviewed by PSAG

It was noted that all products are now in the UNOS Connect Learning Management System (LMS) and all will be offered for CEPTC credits. The available data has shown that overall the community has found the videos to be useful and helpful. More evaluation and assessment data will be available in the future. The safety series is being repackaged for CEPTC credits since the first three were released prior to the LMS starting.

7. Policy Oversight Committee Updates

Vice chair, Dr. Michael Marvin, provided the Policy Oversight Committee (POC) update. He shared an overview of what the POC does and what types of items must be approved by the POC. POC is vice-chairs of all Committees. The 2015-2018 OPTN Strategic Plan goals were reviewed along with the level of effort (LOE) assigned to each. Members were shown how the actual project portfolio LOE by goal fits against the plan benchmarks. They were also shown how to access the dashboard should they want to review it on their own.

The new fiscal impact process for proposals was also discussed. Fiscal impacts to small, medium, and large organizations (e.g. transplant hospitals, OPOs) will now be part of information sent to the OPTN/UNOS BOD when considering policy proposals. The fiscal impacts are high-level estimates developed by an ad hoc fiscal impact group that contains both Committee and non-Committee members. The pilot process has both OPTN member as well as UNOS staff input in developing high-level fiscal estimates for low, medium, and high volume organizations impacted by the proposal.

8. Transportation Risks for Transplant Professionals

The Committee reviewed the draft transportation survey. They decided to make edits and then move forward with sending out the survey.

At the April 2016 in person meeting, Dr. Marlon Levy shared his experience with an accident involving ground transportation arranged by an import OPO. He urged Operations and Safety to look at this issue and that the Committee had an obligation to the community and transplant professionals. The Committee formed a small group and decided to work towards a non-policy option that could educate the community. The goal is to find out what various ground transportation practices are, and perhaps identify best practices.

What to consider with transportation had received attention following a serious air accident occurring over a decade ago and resulting in several deaths. As part of this effort, the community was able to learn about what to look for in air transportation such as Argus rating based on necessary maintenance and what insurance thresholds are needed. It also encouraged transplant programs and OPOs to develop internal policies. The Committee is hoping to facilitate dialogue, learn current status, and make recommendations for what needs considering for ground transportation. There needs to be a sensitivity to knowing vendors, having standards, and developing internal policies.

The Committee reviewed a draft survey. A number of edits were suggested. These include being more specific about ground transportation being inclusive of transportation to the airport; splitting up questions for practice by within and outside of the DSA; being inclusive of both transport personnel as well as OPO personnel that travel for recovery activities; and types of ground transportation used. The Committee decided to limit history of accidents to the past five years. The survey will query about restrictions, protocols, or requirements for various types of ground transportation. The survey will be designed to allow for differences by organ. The Committee discussed when donors are transported to central places but ultimately decided to limit this survey to transportation of recovery staff.

The Committee discussed that surgeons are asked to drive themselves and that the liability and safety concerns need to be considered. In addition, students may be included in recovery trips but may not have actual coverage. Members spoke about personal issues with driving as well as safety concerns regarding taxi drivers and their vehicles. It was also noted that ambulances may not be considered safe.

The Committee debated whether to include air transportation in the survey as separate questions. They decided to do so to update previous work. A survey conducted by ASTS in 2010 was identified and included some ground transportation questions. The group will try to use those questions where possible.

Once edits are made, the draft survey will be shared with the group for final approval and then go the UNOS survey group for its feedback. The group discussed how to distribute the survey and plans to use ASTS, AOPO, NATCO, Transplant Administrators list serve, and a Transplant Pro link through a preliminary article. The survey will be built using REDCap. A voluntary identifier will be part of the survey to try to account for multiple responses from one organization.

Upcoming Meetings

- November 3, 2016 Teleconference
- December 1, 2016 Teleconference
- January 5, 2017 Teleconference
- February 2, 2017 Teleconference
- March 2, 2017 Teleconference
- March, 28, 2017 Chicago, IL

- April 6, 2017 Teleconference
- May 4, 2017 Teleconference
- June 1, 2017 Teleconference