OPTN/UNOS Operations and Safety Committee Meeting Minutes March 28, 2017 Chicago, IL

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

Introduction

The Operations and Safety Committee (OSC) met via Citrix GoToTraining teleconference, in Chicago, IL on March 28, 2017, to discuss the following agenda items:

- 1. Infectious Disease Verification Project
- 2. Explaining Risk Related to Use of US PHS Increased Risk Donor Organs
- 3. IT Pathways
- 4. Extra Vessels
- 5. TransNet
- 6. Patient Safety Data Review
- 7. ABO Post Policy Implementation Evaluation
- 8. OPTN Board Membership
- 9. Policy Oversight Committee (POC) Update
- 10. Systems Optimization Project
- 11. Transport Survey
- 12. New Project Ideas
- 13. Other Significant Items

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

1. Infectious Disease Verification Project

The Committee was informed of discussions with the Membership and Professional Standards Committee (MPSC) leadership that led to the decision to end policy development for this project.

Summary of discussion:

The Committee was informed of discussions with leadership from the MPSC regarding the infectious disease verification proposal. MPSC leadership conveyed through discussions and a formal memo that they do not support going forward with a policy proposal. They do support education efforts. The Committee had already decided to use infectious disease verification as the topic for their next patient safety video product. The POC approved project will be ended in light of this feedback.

After the first public comment round with this proposal, Committee leadership sought feedback from the original proposal referral source (MPSC). Through Committee leadership discussions, it became evident that a policy proposal was not the preferred pathway. The OSC chair read part of a memo received from the MPSC:

"We also revisited the enclosed 2014 memorandum, which suggested that the OPTN consider whether policy should require double verification of infectious disease testing results. We acknowledged that the memo was likely written in response to a small cluster of near miss events from 2011 – 2014. However, the data since this time does not show that the trend has continued. We understand that many programs have already developed and implemented processes to reduce the risk of infectious disease transmissions. The lack of such transmissions

suggests that these practices are effective. Moreover, the MPSC already has sufficient authority under existing policies and bylaw requirements (namely Appendix L, Sections 15.4 and 15.5) to engage members who do not have necessary safety checks in place. For all these reasons, the MPSC leadership do not believe the need for additional infectious disease verification policy requirements exists at this time."

The Human Resources and Services Administration (HRSA) representatives indicated that they were not opposed to stopping policy development. All stakeholders agreed that education efforts would be sufficient. OSC leadership was appreciative of the communications that provided a clear pathway for future efforts. The subcommittee chair was recognized for her efforts on this project.

The Patient Safety Advisory Group (PSAG) had already decided to pursue living donor infectious disease verification as their next safety series topic. The Committee discussed if there were other additional areas where education might be pursued such as a Transplant Pro article or a toolbox. These might be developed as resources to support the patient safety education project in development.

The Committee was also provided some advice about how efforts to address problems can vary in the level of prescriptiveness and monitoring. In some areas, it can make sense to provide more discretion and multiple options while in other areas the need may mean providing fewer options depending on the issue.

The Committee also discussed possibly bringing this topic to conferences such as Transplant Quality Institute (TQI) where there is growing attendance and opportunity to discuss these types of issues. The Committee is working on an abstract for ABO verification for this conference.

Next steps:

-The PSAG will continue developing the living donor infectious disease verification topic for the next patient safety product. The formal OPTN project to develop policy will be cancelled.

2. Explaining Risk Related to Use of US PHS Increased Risk Donor Organs

The Committee received a presentation from the Ad Hoc Disease Transmission Advisory Committee (DTAC) on their current public comment guidance proposal "Guidance on Explaining Risk Related to Use of U.S. PHS Increased Risk Donor Organs When Considering Organ Offers".

Summary of discussion:

OSC members recognized the significant need for this guidance document. They expressed overall support for these efforts. They noted that the guidance document will greatly help the transplant community become more informed and hopefully assist with improved patient education and use of increased risk donors.

The Committee discussed variabilities in clinician opinions and patient communications regarding the willingness to accept increased risk organs. Issues regarding pediatric donors were also highlighted, as many programs do not currently consider using these organs. It was asked if there any new pediatric data. It was noted that the risk might be low enough for some in the pediatric community to revisit their decision-making. The Committee requested more specific data and guidance related to pediatric donation and transplantation.

The Committee noted the overall low risk especially when compared to other risks such as a motor vehicle accident or remaining on dialysis. It was suggested that DTAC emphasize that 99.7% of these organs do not transmit disease and to publish actual numbers of increased risk

organs (and non-increased risk organs) transplanted along with the actual numbers that transmitted disease.

One member also noted that treatment options are more available for HIV and HCV and that can change consideration of using these organs since if the rare transmission occurs it is treatable. Another member noted that this was selected as a priority topic by the Alliance and greatly needed.

Next steps:

The Committee will submit a formal public comment in support of the proposal with requests for additions of actual transmission data and specific pediatric information. Committee members were asked to consider the specific feedback requested on institutional experiences and challenges with increased risk donor organs and to provide individual public comment. Committee members were urged to consider attending the upcoming webinar on April 4, 2017.

3. IT Pathways

Alex Tulchinsky, UNOS Chief Information Officer and Amy Putnam, Director of Customer Advocacy traveled to the OSC meeting and presented information about information technology (IT) directions as well as different pathways for IT projects (OPTN/UNOS Board of Directors and Customer Advocacy).

Data summary:

The recent history of UNOS IT development was shared. Several years ago, a significant backlog of IT work approved by the OPTN BOD existed. This backlog has been reduced. Following the next BOD meeting where new work is generally approved, there will be only a three-month interval between approval and commencement of work.

IT has also been developing plans with other issues in mind. During the period of high backlog, there was not capacity to work on community requested projects. As workload has shifted, IT has made changes to help address other IT enhancement needs. The customer advocacy process for IT projects was outlined. These projects do not include new member requirements (policy) or increased data burden. Potential projects can come from members of the community, Committees, or staff. Ideas are put through an intake process where they are evaluated by internal staff as well as the Customer Council, a body of 15 transplant community members. Ideas must be relevant and have impact on a significant volume. If accepted during the intake process, then requirements are drawn up for advocacy ideas. Committees might be used to provide feedback, particularly when they submit ideas. Following requirements gathering, these type of projects will be prioritized and put on a road map. This part of the process is still in development. The Customer Advocacy Department is piloting a way that all members can see these ideas, provide comment, and vote on their prioritizes.

In 2015, 76% of IT work was related to OPTN work (policy/BOD approved projects). This was reduced to 52% in 2016. The goal for 2018 is to spend 40% of efforts on OPTN and 34% on community (Customer Advocacy) work. The remaining percentages are targeted for 16% technology (upgrades) and 10% department (internal).

Currently the Advocacy Department has several projects in various stages of development:

- Systems Optimization
 - Improvements to DonorNet
- Addition of 3 other fields to DonorNet
- Patient Safety Contact
- Sharing Post Recovery Test Results

• Pre-recovery Verification for Living Donors

An update on DonorNet Mobile projects in flight was given. The OPO Version (Phase 1) will provide functionality to view donor and provider information, verify ABO, upload donor attachments, and view donor attachments. It is in the pilot phase with plans for full deployment on April 24, 2017. A transplant center version where members can view complete donor record, view and respond to offers, and view basic candidate information is slated for release in late 2017. Phase two of OPO enhancements will allow for verification of ABO subtypes, viewing the complete donor record, and sending offers. This is targeted for release in late 2017 or early 2018.

IT needs in the transplant community include more efficient ways to review and share data. It was noted that UNet infrastructure is quite intertwined and that has slowed the ability to provide enhancements since the underlying architecture is not easily compartmentalized. It was also discussed that currently users may have multiple points where data must be entered. The goal is to have one point of manual data entry and that data end up in whatever system (UNOS or individual organization) that is needed. IT has been striving to work with electronic medical record (EMR) vendors to facilitate the building of APIs on both the UNet and EMR ends so that data can be exchanged seamlessly and efficiently. This big endeavor will take several years.

IT also shared other new projects such as developing a cloud imaging system. All systems could provide and access imaging related to transplant using this solution under development. This would eliminate less efficient and timely means of data sharing by paper, fax, disc, etc.

Summary of discussion:

The Committee was very thankful for the in-person presentation. They are supportive of these efforts. It was noted that many of the ideas for TransNet that had been listed and followed before would now fall under the advocacy versus a policy pathway.

The Committee asked how a backlog of customer advocacy projects will be prevented. IT will need help from Committee and community to decide top priorities.

The Committee discussed pros and cons of EMRs and APIs to achieve Transnet needs. On one hand, having APIs between EMRs and UNet would be very helpful. It would assist with many tasks such as verification. On the other hand, Committee members worried about UNet API development being a priority for EMR vendors (transplant is relatively small in health care) and for hospital administrators. Others talked about version and module issues as there is variation in where hospitals are and whether they use specific modules such as EPIC's Phoenix transplant module versus just an OR module or base package. Some fear this will become too complex to get all approvals needed, enhancements built in the right places that can interface across versions, and implemented within a reasonable time.

The Committee started discussions of an alternate path to provide complete functionality for living donors and TransNet within DonorNet. The idea would be that DonorNet is already in most ORs and that development is under OPTN control. Previous and current concerns revolve around the number of OR staff that would need access (100s in some institutions). This issue would be manageable if each individual organization's UNet system administrator could grant and manage access versus for their employees versus having to go through UNOS. In addition, it would need to be for an extremely limited role and only to perform necessary OR functions (e.g. check-in, verifications). IT responded that this was doable from a technology standpoint. It was also noted that the current TransNet is built this way. Access is web-based and does not require UNet access for check in. It was also noted that access could be a favorite site in the OR as ORs now do have internet access. One issue would be the need to have a complete package. Currently, living donor data collection is not within DonorNet. This would be a

significant area to address. The ability to perform check-in and verification within the system would be necessary. For the OR to have different processes for deceased and living donors is too complex. Currently living donors are in a different system that does not have the same information or features as deceased donors. Adding living donors and match functionality to DonorNet is a significant undertaking partially due to the age of the system. It is possible but not simple.

Next steps:

The OSC and IT leadership requested that members go back to institutional stakeholders, such as OR staff to solicit ideas about what would make the most sense for future directions. It was decided to keep the conference call scheduled for April 6, 2017 to continue this discussion.

4. Extra Vessels

The Committee reviewed results from a data request and analysis conducted for the post policy implementation requiring vessels disposition reporting to the OPTN within seven days after the final disposition. This policy was originally passed by the OPTN BOD in November 2012. The policy went into effect in November 2015 following programming of a comprehensive vessels reporting database.

How to access the new extra vessels educational product was demonstrated.

Data summary:

It was noted that this was the first analysis of vessel disposition reporting following implementation of the database. These data are the result of the formal Committee data request and a few additional items.

From January 1, 2016 - December 31, 2016, there were 9,572 vessel disposition reports and 99.6% of donors with at least one organ reported as sent with vessels were reported in the vessels database. It was not possible to do an organ level analysis, as there is no formal tracking of numbers of vessels.

Key statistics on vessels disposition included that 79.0% were destroyed, 19.2% were transplanted, 0.7% (n=69) were sent to another hospital, and 1.1% were listed as "other". The majority (91.8%) were reported using the new system (not at Waitlist removal). 11% were reported late (more than 7 days from transplant or destruction date). 2.8% (n=269) were stored more than 14 days. Only 0.1% were not reported within 21 days from recovery date (n=9).

Of those vessels that were transplanted (n=1,838), 347 vessels were used in 288 transplants of secondary recipients (19%). Fifty transplant hospitals reported use of between 1-10 vessels in secondary recipients. The complete data report is available on the OSC Share Point site or by request.

Summary of discussion:

The Committee noted the tremendous improvement in vessels dispositions following the policy implementation. The vice chair noted that the data shows the importance of having these vessels. Several hundred patients had better outcomes due to the ability to use in secondary recipients and this demonstrated that the use saved more lives and was greater than the risks of identified issues.

Consent for the recipient of an increased risk donor vessel was discussed and it was noted that it might not be feasible due to the emergent nature of use of these vessels in secondary recipients. One program noted that they do not store these vessels to avoid this issue. It was asked if we could look at data regarding increased risk status.

Next steps:

The Committee formally requested that U.S. PHS Increased Risk Status be added to the data analysis. The Committee questioned whether this analysis could include reporting that identifies potential storage of vessels prohibited by policy (e.g. HCV positive vessels).

5. TransNet

The Committee received an update on TransNet OPO usage as well as an update on the status of beta transplant hospital participation. The Committee discussed potential modifications to TransNet programming and the extra vessels label to update both items to reflect multiple needs and changes to infectious disease screening. The Committee also discussed recommended next steps for TransNet development.

Data summary:

The most recent OPO usage data was reviewed. In February 2017, there were 546 TransNet cases created and 520 cases where TransNet was used to ship at least one organ. This equates to 71% of all recovered donors that had a case started and 68% of all recovered donors that had at least one case completed using TransNet.

Summary of discussion:

It was requested that we would start looking at all 58 OPOs versus training cohorts after the June 1, 2017 implementation. It was mentioned that UNOS plans to launch a portal where members can monitor their own usage. TransNet staff reported that all OPOs had been trained by the end of February. Eighteen transplant hospital facilities are performing check in/match. Staff are monitoring OPOs with no or little usage and have reached out to make sure they have usage plans.

It was noted that the UNOS Executive team will also be monitoring TransNet usage. It was noted by IT staff that available data being used for monitoring would be shared with the Committee as well.

The Committee discussed recommendations from the TransNet workgroup to align the vessels label and TransNet programming for the vessels label with the DonorNet infectious diseases screen. The first two are different from DonorNet. The work group discussed these issues at their last call and came up with recommendations for several items:

- Regrouping the order of tests on the polyplastic vessels label to be grouped by HIV, HBV, and HCV testing at the top. This will allow for quicker identification of vessels that cannot be stored.
- To change some of the test names included on the label and add HIV Ab/Ag, EBNA, and Toxo IgG as test rows. Tests not required by policy such as HTLV would be removed from the label as a standard. They would be possible to be populated in one of the three "other" options that could become part of an automatic drop down selection.
- Modify DonorNet to add three "Other" fields" with common test name dropdowns (e.g. HTLV, Strongyloides, West Nile Virus). This would be a drop down versus a free text. By programming this in DonorNet, it will allow results to be exported directly into TransNet versus requiring them to be typed into the TransNet application as is done right now.
- The test results would be modified to match each other. The confusing choice of N/A would be removed from the vessels label. Indeterminate and pending would be added to the vessels label (It would have five versus four columns). The unknown option in DonorNet should be eliminated. It was criticized as an ambiguous option. It was used

only 10 times in 2016 and five were for HTLV cases. It is an artifact that is now outdated and should be retired from being a DonorNet option.

• The Committee requested some type of option on the label to help avoid storage of prohibited vessels. Several options were discussed but this was one the item where a final decision was not made since TransNet programming might also be the preferred solution.

The Committee supported all of the recommendations. It was noted vessels label modifications and TransNet programming would need to be completed concurrently and released at the same time. This programming will occur after VCA TransNet programming approximately in the first quarter of 2018. The Committee will review and finalize recommendations at a future meeting.

The Committee discussed possibly having a smaller transplant hospital TransNet project that might provide a foot in the door related to vessels. A TransNet scan could be programmed to call up the most recent infectious disease results from DonorNet and that could help with verification prior to implant. After the OR, the vessels label could be scanned to record disposition (e.g. storage). If a vessel with an infectious disease result showing that the vessel cannot be stored a warning would pop up. The benefits here would be real-time infectious disease information, real-time vessel data entry exported from TransNet to TIEDI, ease of training, and minimal equipment required as the scan could be done with a phone.

It was noted how all facilities struggle with vessels management. All of this would be a real time scan with real time information. There could be enhanced monitoring and transparency with this functionality. The equipment needed would be access to the web site using any web compatible device (e.g. tablet, phone). The user would need a scanning app (Download Apple or free android) or the organization could purchase a two-dimension bar code scanner. This can be hooked up to a computer via a USB port. It could be a selling point to help transplant hospitals be compliant with vessels policies. One member commented that saying a system is required is what causes movement at this institution.

It was noted that whatever functionality is built that the EMR interface is an issue and a need consistently raised by the Transplant Administrators Committee (TAC). Using different systems is also a concern as discussed earlier. It might be easier to allow the scan to occur using the EMR system and this could increase buy in.

The challenges though of EMRs were revisited. One member explained that they still do the ABO verification on paper but that is the only function still on paper. The goal though is to make it work through the OR and not to use paper anymore. One member has had conversations with EPIC. It seems that they have plans to work on verification in the OR module but not until 2018.

Issues with the packaging and labeling of living donors were discussed. There are so many variations in how this is done and UNOS needs help from the Committee to move forward to get the Road Map for TransNet. In TAC discussions, TransNet always falls back into conversation. They want a complete product including living donors.

It was also noted that once any mandatory policies are approved that a long lead-time of several years (3-4) should be given as hospital budget, security, and IT systems must be involved and moving through the bureaucracy can take a long time. It was reiterated that not having a complete package and having the two processes for living and deceased donor is torture for training and ability to comply.

Some hospital systems do not want another window and do not want to train people on more things. The Committee grappled with what is the most practical approach. IT has asked that these discussions continue to help give them direction.

Many noted that if the solution provides a process that is close to guaranteeing compliance with ABO that is a big selling point. One member asked if a voice option (like Alexa) could be developed. No one would have to leave the bedside and there would not be a safety concern.

Next steps:

The Committee will continue to monitor OPO TransNet usage. The Committee will continue with plans to modify TransNet and the vessels label as discussed. The Committee will continue discussions on the best way to move towards broad and eventually mandatory transplant hospital TransNet usage. The discussions over the most efficient and path of least resistance will continue.

6. Patient Safety Data Review

UNOS staff presented data related to patient safety reports and investigations. The OSC reviews patient safety situations (including both adverse events and near misses) submitted to the OPTN Improving Patient Safety (IPS) portal and other pathways every six months. This is done to help the committee identify safety gaps, address high frequency and/or high impact events, and identify if specific events are becoming more frequent or associated with loss of organs.

Data summary:

Data from all of 2016 were analyzed and presented. The categorizations of events are done by UNOS patient safety staff following the conclusion of a safety report investigation. Post-case review provides robust and comprehensive classifications and outcome determination. Cases were categorized into one or more high-level, as well as possibly one or more subcategories. Since the last analysis there has been the addition of 'Non-issue/Reported in error' field in primary event categorization. More information was examined for cases that had organ non-recovery, organ discard, and/or added cold ischemic time (CIT).

There were 333 cases reported in 2016. Of these, 156 (46.8%) were through the online Improving Patient Safety (IPS) portal IPS; 120 (36%) were through the UNOS Research Department; and 57 (17.1%) were from "other" pathways. "Other" pathways included emails, phone calls, patient complaints and other UNOS departments.

Labs were the subject of 16 events (4.8%). OPOs were the subject of 120 events (36%). Transplant Centers were the subject of 197 events (59.2%). The top three high level categories were transplant process/procedure (n = 97); data entry (n = 38); and communication (n = 35). Ninety-four of the transplant procedure/process cases were subcategorized as 'other'. These included 49 (52.1%) cases involving prohibited vessel storage and 41 (43.6%) cases involving vessel sharing. A closer look at the data entry errors showed that the most common were HLA and SSN data errors. Under communication, the most common findings were change in test results not reported (n=8), inaccurate/insufficient donor or (organ/extra vessels) information (n=7), and increased risk (or high risk) status of donor not communicated (n =6). Most test results not reported involved results received post-transplant.

For the outcomes analysis, 32 cases were categorized as a non-issue/reported in error and excluded, thus leaving 301 cases for this part of the analysis. There were 21 instances resulting in organ non-recovery, 20 instances resulting in organ(s) discard, and 17 instances resulting in delay/added CIT. Fifty five cases had a single outcome out of these three. There were two cases that resulted in the delay and discard of at least one organ and one case resulted in the non-recovery and discard of at least one organ.

Among the 21 non-recoveries, there were 19 living donor (LD) adverse events and all were aborted recoveries. Among the 20 organ discards, eight were recovery procedure/process

events and five of the eight were subcategorized as an injury to organ or vessels. Of the 17 delays/added CIT cases, there were six related to packaging/shipping and five related to transportation.

For 2017, several additions to the database and report are planned. These are to include a self-reported event field to track over time, the reporting member type, and additional information on living donor aborted procedures (donor vs. recipient related).

An update was given on the Healthcare Performance Improvement (HPI) work to introduce harm classifications was given. UNOS staff were trained on-site by a consultant in December 2016. The HPI method uses a systematic process to identify a deviation from standard practice and if that deviation reached the patient then a level of harm associated is applied. The patient safety team is using a standard set of rules and has applied harm classifications to 167 cases from January-June 2016. This method involves analyzing OPTN patient safety events from individual patient level perspectives.

Data on the six patient safety series products developed and released since June 2015 were reviewed. The data included date released, number of views/registrations, date of last view, assessment gaps, and general comments. A summary of these data are below.

Title	Date	Views - Registrations	Last View	Assessment Gaps
Proactively Avert Errors	6/3/15	684	3/19/17	Risks in the transfer of patient care
Organ Discards	10/29/15	499	3/23/17	Communication between the OPO and Recovery Surgeon
Hemodilution Errors	1/28/16	325	3/19/17	Need to assess samples for hemodilution, practices to help avoid hemodilution errors
ABO Verification in the OR	5/4/16	2596	3/23/17	Confirming donor and recipient compatibility or incompatibility
Allocation Deviations	8/23/16	254	3/22/17	Sources to confirm allocation deviation decisions
Extra Vessels Handling and Storage	2/28/17	77	3/24/17	Extra vessels that cannot be stored, setting third party expectations

Summary of discussion:

One item raising concern and question was the 19 LD aborted procedure adverse events. It was noted that more information is needed. For example were these cases where something happened to a recipient or something that could have been known ahead about the donor. It was noted that there are plans to further analyze these cases and that both staff and other Committees are looking at this finding as well.

The Committee requested a list about all research reports being generated. It was asked if we were able to determine if events identified by research reports should have been reported by the member. It was explained that this is a voluntary system so that question would be difficult to answer. It was noted that if a report was received by both channels that a mechanism exists to identify duplicates. Duplicates are linked and counted as one case.

Most of the cases identified through research are vessels cases. One member commented on the value of getting to back-end data. He stated that if we use it in a way to improve outcomes without being punitive it could improve processes. In absence of data, no one knows what is going on and they might be afraid to report. The whole process can affirm and help understand patterns for things that are self-reports, site survey findings, It was clarified that items coming from research are purely from programmed data reports and that site survey findings end up in the "other" category.

One member did ask about getting more blinded investigation data from MPSC. While there is not an update to that question, it was noted that there is a culture shift at UNOS with an emphasis on operationalize practices differently to be fair, treat all the same, and be less punitive.

The success of the patient series was noted as an effective collaboration between the PSAG and UNOS staff. The brainstorming processes have gone very well. It was noted that in the last production on extra vessels that summary (de-identified) data from root cause analysis and correction action plans were used to help guide the development to assist with prevention of prohibited vessels storage. It was noted that this effort also was requested by the community and is an example of how we give value back to membership. This effort is more in alignment with what the transplant community has requested: not more policy but assistance in how to comply with policy.

Next steps:

Patient safety data analysis will continue to be conducted and presented every six months to the Committee.

The PSAG will continue collaborating with UNOS staff to develop quarterly patient safety products including work on the current living donor infectious disease verification educational offering.

7. ABO Post Policy Implementation Evaluation

The Committee received an update on the status of the ABO post policy implementation evaluation.

Data summary:

Data on which indicators will be tracked and presented at the next in-person meeting were discussed. The post-implementation indicators originally proposed include:

- Number of patient safety situation reports regarding labeling, typing, reporting, and verification errors related to ABO
- Number of patient safety situation reports reflecting an unplanned ABO incompatible transplant
- Number of patient safety situation reports reflecting a transplant of the wrong organ into the wrong recipient (or near misses)
- Number of candidates transplanted not appearing on match run (NOMR cases)
- Number of corrections made after initial entry of candidate and donor blood types
- Number of persons completing ABO proficiency training

The education resources accessed for ABO will be used as a proxy for training.

Summary of discussion:

OSC members requested that survey data related to ABO policies be incorporated into the implementation evaluation. It was noted that volunteers are also working on this topic for a TQI abstract.

Members were alerted that recent questions related to ABO were in their meeting packet. None appears to rise to the level of needing evaluation for action beyond the request for building the living donor organ verification link (OVL). External review and finalizing of requirements will be done next. The project has not been put on a road map yet. IT also received a request to build a link to download the URL for the deceased donor OVL report. Members noted that there are multiple ways to do this already. A FAQ on how to do this for Macs and PCs would be a more efficient use of resources.

The chair raised the need to update an existing guidance document on subtyping. Several needs exist. These include updating vocabulary used in the document to be consistent with recent policy changes, reviewing the information for currency, updating an old kidney policy section, including relevant FAQs/other resources recently developed, and adopting a plain language approach. The subtyping module recently developed in UNOS Connect directs members to this guidance on the OPTN website. The need to have some assistance from professionals with knowledge in this subject area was noted. The Committee has worked with the American Association of Blood Banks and Christopher Bryan, a subject matter expert in the past. Updating the guidance would require POC approval and public comment as guidance document.

Next steps:

Committee volunteers will work with UNOS staff to submit a TQI abstract. The Committee requests that site survey findings related to ABO be added to the post-policy implementation evaluation. Feedback will be shared with IT that developing instructions on downloading URLs and OVL reports would be better than programming a button for the URL to download. A project form to update guidance on subtyping will be developed for submittal and POC consideration.

8. OPTN Board Membership

The Committee received a presentation about the process for OPTN/UNOS Board of Directors (BOD) recruitment and election.

Summary of discussion:

The Committee received a presentation about the process for OPTN/UNOS Board of Directors (BOD) recruitment and election. More efforts are being made to assess the needs and effectiveness of this group. Recruitment and call for nominees are starting earlier. In addition, there is now a preference to have nominees that have previously served on an OPTN/UNOS Committee, as they will be more informed of process and issues.

Some of the overall BOD membership guidelines were shared. There are 42 members of the Board of Directors and the composition is largely influenced by the federal statutes and regulations. The Final Rule and the OPTN Bylaws establish that approximately 50% of the Board must be surgeons or physicians. Among this category, there are certain specialties that are mentioned as well, such as the need for at least one pediatric specialist. The Board attempts to have diversity in the organ specific expertise in this category.

Under the Final Rule, at least 25 percent of our Board must be transplant candidates, recipients, organ donors, or their family members, and certain groups must be represented. These groups include OPOs, transplant coordinators, and histocompatibility professionals. Each of the 11

OPTN regions elects a councilor to serve on the Board. Members are elected to one, two, or three-year terms. The President and Vice-President serve a one-year term. All other members serve a two-year term, except for at-large patient and donor reps who serve a three-year term.

Recently adopted job descriptions for the Board Vice President/President-Elect as well as atlarge members were shared. The Vice President/President-Elect must have had prior service on the BOD and either the Membership and Professional Standards Committee (MPSC) or POC. Expectations, such as attending meetings including one regional meeting per cycle, are being shared for all who might be considering service. An annual needs assessment is completed in July to help develop a fall slate that can fulfill identified gaps. Some of the needs identified for this year include those with corporate, non-profit governance, finance, and strategic planning experience. The OPTN will develop a new three-year strategic plan in 2018. Goals are also to improve minority and gender representation as well as improve representation from different professional perspectives (e.g. transplant administrators).

Open positions coming up for 2018-2019 will include officers as well as donor and patient affairs representatives with a need for more recipients; at-large MDs practicing medicine, general atlarge, and transplant administrators. The call for nominations through Committees starts this month and will expand to the greater community in April. Nominees will be assessed through August and a slate developed that is approved later in the year. The election is held in February/March 2018 with a start date of July 1, 2018.

Next steps:

Committee leadership will put forth a suggested nominee.

9. Policy Oversight Committee (POC) Update

The Committee received a presentation on the latest POC update.

Summary of discussion:

The purpose and process of the Policy Oversight Committee (POC) was presented.

The current project dashboard showing alignment with the OPTN Strategic Plan goals was reviewed. It was noted that there is space for new projects in OPTN Strategic Goals 3, 4, and 5. The project portfolio is now at 40% for increasing transplant. Goals 4 (Safety) and 5 (Efficiency) had been over allocated, but now have room. The most recent approved projects were shown. Committee members were shown how to access the project dashboard through the OSC Share Point site. Committee members did not have any questions.

Next steps:

The OSC will consider the current project portfolio as they start working on potential new projects.

10. Systems Optimization Project

The Committee received an update on the Systems Optimization project led by the OPO Committee. OSC does have a representative on this work group.

Summary of discussion:

This project will involve a policy proposal being developed for fall public comment. The proposed policy would:

 Reduce the current time limits for responding to electronic organ offers from 1 hr/1 hr to 30 min/30 min

- Add additional time limit of 1 hour to make a final decision once all required information has been provided
- Limit the number of offers that can be accepted for one candidate
- Require OPOs to manage match run acceptances in real time
- Revise or create definitions

In addition, DonorNet enhancements to provide automated notifications are being developed using the Customer Advocacy pathway. The group will also evaluate transplant center acceptance criteria and acceptance practices.

OSC members provided the following additional feedback:

Concerns were expressed when the clock for final acceptance would start because it could be that repeat testing (current echocardiogram for pediatric organ consideration) might be needed before the final decision. Transplant programs do not want to turn down and organ because there will not be time to get the information to inform a final decision.

The criticality of updating DonorNet mobile was stressed if time limits go down to 30 minutes since using the phone to evaluate offers will be a necessity. There may not be enough time to find a computer and login to evaluate offers within the proposed times.

It was noted that transplant hospitals often do not see when an acceptance (green check box) has been entered on the match run. Members commented that practices vary by OPO and that transplant hospitals cannot see the final acceptance until the OPO enters the data. It was brought up that part of the proposal would require the OPOs to manage the match in real time, which would help address that concern.

The change from a vertical to a horizontal system was noted. The importance of having valid primary backups was noted. One program shared that they actually admit primary back-ups so they are ready to go should the offer come to them. The proposed ideas should help improve efficiencies. The need to evaluate transplant center acceptance criteria and practices was also noted as an important step to reduce inefficiencies in the current system.

Next steps:

The Committee provided feedback to the OPO liaison. OSC will continue to monitor and participate in this project.

11. Transport Survey

An update was provided on the status of the transportation survey under development.

Summary of discussion:

The survey group has continued to work on a draft transportation survey to do a preliminary assessment of the status and needs of the transplant community. The emphasis will be on ground transportation following a presentation last year by Dr. Marlon Levy who shared his ground accident experience. An internal team at UNOS is now reviewing the survey. Some but not all feedback has been received.

It was discussed that the survey will go out to a broad audience at this time. This is a preliminary effort to determine future direction. Targeting or identifying one person per organization would require significant effort and different positions might have different views. There is a place to identify an organization to help with multiple response from one place.

The Committee noted the great variability in teams and practices depend on the organ and specific recovery team. There are also many differences in contracts, vendors, and thresholds for safety and insurance. Previous efforts focused on flight transportation. The Committee noted

that ground transport is where we are most vulnerable and it is not captured in data. We do hope to get a temperature check, find out about community practices, and gather some preliminary data, as we are likely to see more need in the future.

The group discussed how to disseminate the survey. They do plan to use TransplantPro. It was decided not to use list serves, as those seem to be too open.

Next steps:

Once remaining survey reviewer feedback is received, members working on survey development and will make edits as needed. A final draft will be circulated to the Committee.

12. New Project Ideas

The Committee reviewed ongoing and potential new project ideas.

Summary of discussion:

With the changes in Committee activity, members were asked to think about next steps. We are an operations committee. Good systems incorporate safety in their design. Members were challenged to think about possible future directions. They were challenged to go back to their own institution and start asking questions about what are things that you think we could do differently and better.

One emerging issue that was discussed was emergency preparedness. It was noted that new CMS regulations go into effect in November and some organizations may be scrambling at the last minute. Members talked about their own drills or real experiences. The most challenging issue was related to lack of internet or cellular services. Members were urged to think through how an alternative process might work. While organizations might have plans, there is a need to evaluate how they would work for transplant. Geography and types of disasters depending on location was another pertinent consideration mentioned. Building a toolbox with resources was suggested. It was also suggested to amend the membership database so that credentialed personnel can be accessed. This functionality could also facilitate sharing and reciprocal privileges that might be needed in emergencies to avoid patient disadvantaging.

Next steps:

Ideas will continue to be evaluated and possibly submitted for formal POC project approval or through the Customer Advocacy pathway. Ongoing efforts include the transportation survey and, depending on the findings, a project might be pursued. The Committee will continue with the patient safety education series (this is an education effort not requiring a POC approved project). Other potential projects being developed include TransNet/DonorNet OR functionality, vessels label and TransNet modifications, and revising the subtyping guidance. The other potential idea was to consider some type of assistance for emergency preparedness. Members were asked to come up with at least one idea from their organization for how the OPTN could do something differently or better than is currently in place.

13. Other Significant Items

Committee members who would be completing their service on June 30, 2017 were thanked and recognized. These members include Dr. Michael Green, Theresa Daly, Nicole Johnson, Betty Crandall, James Anderson, Diane Bickford, Peyton Gresham, Luke Preczewski, and Michael Seely. Michael Seely was specially recognized for serving over twenty years on OPTN Committees as well as the BOD.

Upcoming Meetings

- April 6, 2017 (Teleconference)May 4, 2017 (Teleconference)