OPTN/UNOS Operations and Safety Committee
In-Person Meeting Minutes
October 23, 2018
Chicago, Illinois

Michael Marvin, MD, Chair
Christopher Curran, CPTC, CPTBS, CTOP, Vice Chair

Introduction

The Operations and Safety Committee (OSC) met in Chicago, Illinois on 10/23/2018 to discuss the following agenda items:

1. Policy Oversight Committee (POC) Update
2. Special Public Comment Liver Proposal: Geography Update
3. Liver and Intestine Distribution Using Distance from Donor Hospital
4. Aviation Trends and OPOs
5. Air Travel Questionnaire
6. Effective Practices Guidance Document
7. Patient Safety Data
8. Other Significant Items

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

1. Policy Oversight Committee (POC) Update

The Vice Chair provided background information and an update of the Policy Oversight Committee (POC). A brief overview of current and new POC projects were also discussed.

Summary of discussion:

Projects must align with one of the strategic goals with the OPTN. The POC has the opportunity to comment on projects before they go out for public comment and make recommendations prior to submitting proposals to the Board. Recent and current work of the POC includes:

- Broader Sharing
  - Helping develop a response to HRSA on the use of DSA and regions in UNOS policy
- Reviewed six policy proposals prior to public comment
- Reviewed two new committee projects, including the OSC effective practices guidance document

The Committee was provided with an overview of the OPTN strategic alignment goals. The Vice Chair noted that much of the effort and resources have been going into broader distribution of organs which falls within the equity in access to transplants goal.

An overview of committee projects was shared with committee members. The current status of projects specific to the OSC are as follows:

- Three projects currently post-implementation
- One board approved
- One in the analyzing phase

UNOS staff noted that the information discussed is accessible to committee members on SharePoint.

2. Special Public Comment Liver Proposal: Geography Update

UNOS staff provided an update on the Geography proposal. UNOS staff noted that the Ad Hoc Geography Committee was meeting later in the day and an update would be coming out by the end of the day.

Summary of discussion:

As of September 25, 2018, most of the regional meetings have been completed. There are three frameworks being proposed for all organ allocation policies moving forward. The three models being proposed are continuous distribution, fixed distance, mathematically optimized boundaries.

At this point, the continuous distribution is the model that has had the most support. The state based model was brought up by Region 3 and would be discussed by the Ad Hoc Geography Committee. The themes that have come out of public comment were discussed as follows:

- Continuous distribution:
    - Will eliminate boundaries or "cliffs"
    - Most flexible
        - Based on multiple variables that would be adjusted (vs. fixed shape)
        - Has potential to prioritize pediatrics and/or sensitized patients
    - Most difficult to explain
        - Would be continuously changing
- Fixed distance:
    - Population density has to be considered
        - Concerns about lines being drawn out over bodies of water
    - Size of the concentric circles (what they should be)
        - Should be similar or larger than current allocation policy (not smaller)

UNOS staff noted that the fixed distance model will be the short term fix for the organ-specific committees in order to eliminate DSA and regions from all allocation policies. The OPTN has committed to a timeline of December 2018 for liver and June 2019 for the other organ systems.

- Mathematically optimized boundaries
    - Middle ground between fixed distance and continuous distribution
    - Boundaries would change based on various factors

The Ad Hoc Geography Committee will vote on one of the three frameworks to be presented to the board for consideration.

3. Liver and Intestine Distribution Using Distance from Donor Hospital

UNOS staff provided an update on this proposal that is currently out for public comment. The Liver and Intestinal Organ Transplantation Committee ("Liver Committee") is requesting feedback on the broader two circles (B2C) allocation model and the acuity circles model. The Liver Committee's preferred MELD threshold is 32 but is requesting feedback on a MELD threshold of 29. The data (as of 10/22) of public comment participation was shared with committee members:

- 240 comments, mostly transplant hospitals
    - 93 from Texas
    - 19 each from New York and California

UNOS staff highlighted the common themes as it pertained to circle sizes. Comments were raised regarding concerns about 250 miles of a hospital including circles that contain a body of water or Canada and there were comments that proposed a more population based approach. There were comments about the two different models; some comments leaned more towards the acuity circle model with an emphasis on the lower mortality rate and less potential variability. UNOS staff noted

that there were also comments voicing concern about the discard of organs. Finally, there is support for the changes in priority that benefit pediatric patients.

The Committee Chair commented on the OSC's work that could help address some of the concerns that are being raised during public comment. Once the information has been compiled, the OSC will share it with the Liver Committee. A Committee member inquired about any comments pertaining to the backup process once the re-allocation changes with liver. There have been a few comments in public comment concerned about the increased travel and whether livers will travel further on the initial allocation and then staying local to the new area on backup.

A Committee member commented on the importance of including the stress broader distribution will have on pilots, the transportation systems, and the additional costs. The Committee Chair commented that this information can be provided individually as well as a committee response. He noted that this information can be provided in the committee's guidance document as well as in the Committee's public comment response. Another Committee member posed the question of when payors would be included, as cost is a concern. The Committee Chair responded that payors would not be included in this proposal, but this point will be part of the guidance document. The focus for the committee is a discussion on how best to mitigate those costs.

The Committee was asked to vote on the following questions in regards to the Liver Committee proposal:

- What is your opinion of the fixed distance? Are they the right size?
    - The Committee unanimously voted in support of the fixed distance proposal and that the size is appropriate.

- Do you support expanding allocation of Blood Type O Deceased Donor Liver in Hawaii to apply to Puerto Rico as well?
    - The committee unanimously voted in support of expanding allocation of Blood Type O Deceased Donor Liver to Puerto Rico.

Next steps:

- Public Comment ends on November 1, 2018.
- Liver Committee meets on November 2, 2018. They will be reviewing the final comments and deciding on what proposal to send to the Board of Directors.
- The Board meeting is on December 3-4, 2018.
- If a proposal is approved during the Board meeting, implementation would begin in the first quarter of 2019. It will start with the changes to the National Liver Review Board followed by the liver allocation changes.

4. Aviation Trends and OPOs

The Committee heard a presentation from an OPO Chief Operating Officer with expertise in aviation and medical transport.

Summary of discussion:

The Committee was provided with an overview of common definitions in aviation:

- Part 191
    - General aviation
    - Not for hire; no money exchanged
- Part 135
    - On demand air carrier; money is exchanged
    - There are protections for safety and operations

- Part 121
  - Scheduled air carrier
- FARs
  - Federal aviation regulations

The Committee was provided with an overview of the trends and projections in aviation:

- Air travel is currently up; airlines are hiring
- Pilot staffing
  - Pilots are retiring – 42% of active pilots will be retiring within the next 10 years
  - As transportation demand increases, there will be a shortage of pilots
    - Prices will go up due to this supply and demand
  - Military is training fewer pilots than ever
    - Budget has decreased their training hours (what would typically be 2500 hours of training is now to half or less that time)
  - After 9/11, training centers for civilian aviation were shut down. This huge gap where training did not occur has resulted in present shortage of pilots.
  - Charter companies are closing their doors due to pilot shortage
- Projected trends for the future:
  - Number of flights going up
  - Cost of flights going up
  - Quality of aviation operations is going down

The Committee discussed the analysis of aviation costs from import and local OPO charges. One Committee member noted that imports are approximately 50-80% more expensive than local allocation.

The Committee was provided with the following aviation tips to consider:

- Transplant centers should be listed as additionally insured and have a COI on file for every aircraft
- Meaningful accreditation
- Training
  - Asking the operator questions associated with training and how pilots are being trained
  - The level of training is minimal; there is a differentiator between what is best practice and what is minimally required
- Federal Excise tax fees – they can be significantly high (believed to be about 6.25%)
  - Exempt for non profit
- Accident investigation – built into aircraft and training; old aircrafts do not have advanced technologies /other advancements as newer aircrafts
- Maintenance – have safety audits done every two years

A Committee member asked about the age of a pilot and the requirements of a pilot being fit for duty. It was discussed that pilots can fly up to age 95 for on demand operations; only a physical is required to be legal.

Next steps:

The committee will review the information and data presented and will incorporate it in the guidance document.

5. Air Travel Questionnaire

UNOS research staff facilitated a questionnaire inquiring about aviation trends seen among OPO's. The highlights of the questionnaire were shared with the OSC.

Data summary:

UNOS research staff provided an overview of the Plane questionnaire results. The questionnaire was a collection of both quantitative and qualitative data; the quantitative data was shared with committee members. The following information collected from the questionnaire were highlighted and discussed:

- 54 out of 58 OPOs responded to the questionnaire

Figure 1. Q1: Are there different requirements for flying organs vs. recovery teams?
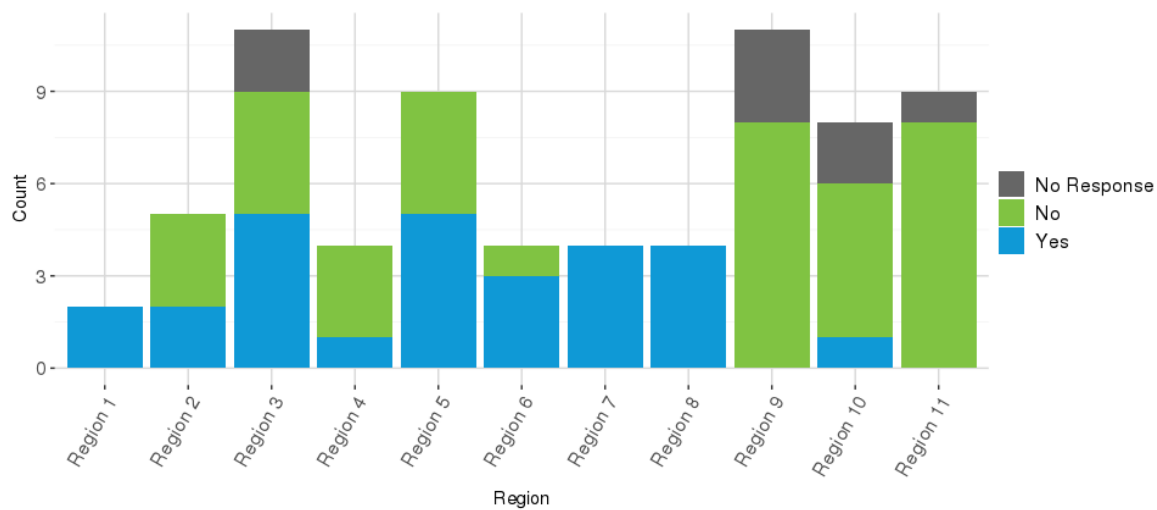
About 50% of the responses indicated that they do not have different requirements for flying organs vs. recovery teams.
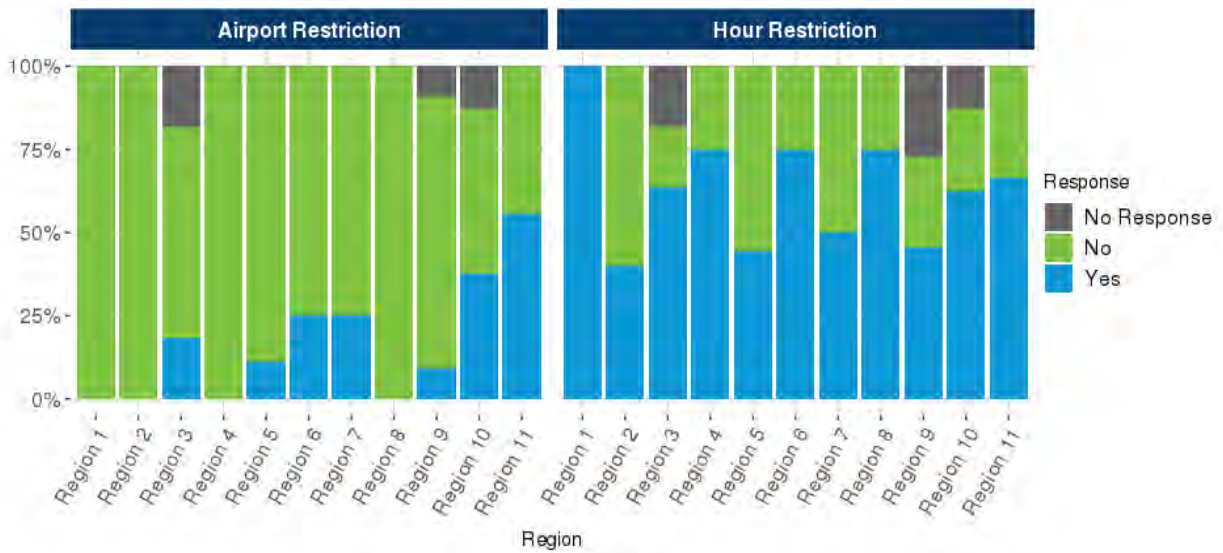
- When looking at the responses on a regional level, there is variability depending on the area
- In context of broader sharing, it would vary by regions; there is variability in the approaches depending on regions and their allocation processes

Table 1. Q2: Are you every unable to find…?

	No	Yes	No Response
Unable to find pilot for surgeon?	40 (56.3%)	24 (33.8%)	7 (9.9%)
Unable to find pilot for organ?	47 (66.2%)	15 (21.1%)	9 (12.7%)
Unable to find plane for surgeon?	40 (56.3%)	25 (35.2%)	6 (8.5%)
Unable to find plane for organ?	48 (67.6%)	17 (23.9%)	6 (8.5%)

The majority of responses stated that there was not much difficulty in finding various factors (pilot for surgeon, pilot for organ, plane for surgeon, plane for organ). There was found to be variability depending on region. A Committee member commented that there is great variability and more difficulty in rural areas. Another Committee member also stated that variability could also be due to how the question was asked and perceived when answering the question.

Figure 2. Q3: Do restrictions ever influence recovery…? (%)

The vast majority of responses stated that there were no restrictions due to airport but there were restrictions due to pilot duty hours. When looking at the responses regionally, Region 11 reported airport restrictions (over 50%). A committee member commented that airport restrictions became inaccessible after a certain time.

The proximity of the donor hospital to their airports explains the restrictions that occur in certain regions.

Figure 3. Percent of Organs traveled by Air
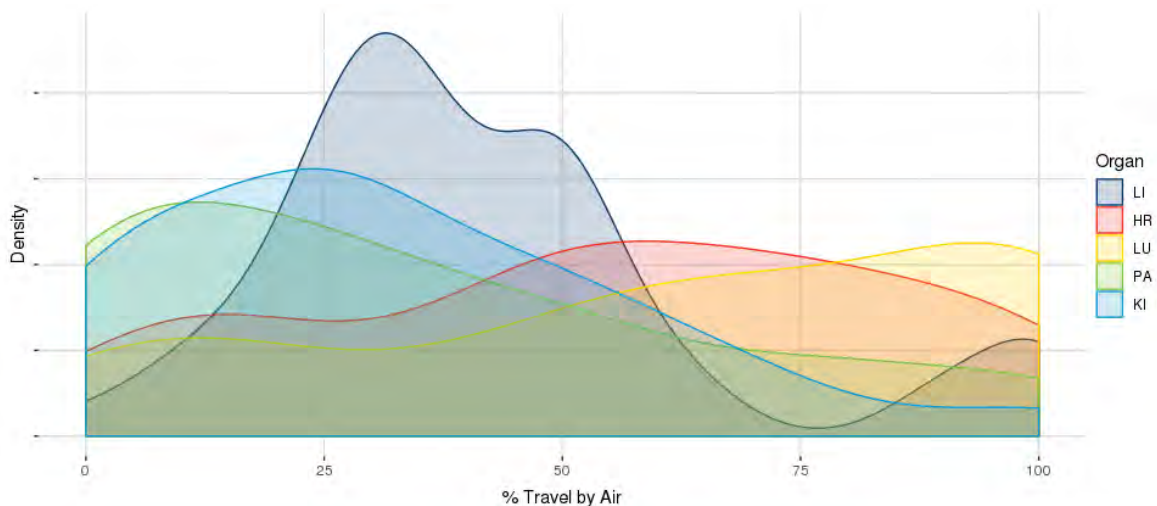
Livers are transported more than any other organ.

Summary of discussion:

Committee members discussed the variability in the data and agreed that the data from the questionnaire was more anecdotal. The answers may be somewhat skewed based on how the questions were asked and who specifically answered the questionnaire (senior administrator vs. transplant coordinator) as well as the region of the OPO. When analyzing the questions by region, there is great variability and OPOs have regionally specific policies and processes.

The Committee Vice Chair commented that the variations correlate with the disparities within the regions where the potential donors are located. In some regions, the donors and donor hospitals are close to the airports where the travel air time is very low; in other regions, the travel time may be increased because the donors come from non-transplant programs.

A Committee member commented on the data has demonstrated that there is a lot of variation, resources already being implemented and some risks that will be present with allocation changes. Committee members agreed that the lack of standardization makes for a better story when looking at the data qualitatively because the wholes can be filled by the stories that have been told during data collection. This questionnaire provides the opportunity to:

- Build a type of survey to yield specific data elements
- Evaluate data collection tool for future data

Next steps:

- UNOS Research staff will refine data
- The data collected will be used to provide a report to the Liver Committee

6. Effective Practices Guidance Document

The Committee worked in groups to develop themes that will form the foundation for a guidance document that will go out for public comment.

Summary of discussion:

The assigned groups provided a report of their discussions and findings. Their responses are as follows:

- **Group 1: Air travel Policies and Charter Availability**
  - Who handles the flights?
    - Differs for each OPO
    - Decision can change based on organ or transplantation site
  - Factors affecting decision air vs ground
    - Time trumps miles (always)
  - Policy:
    - Common theme: Max number of hours for travel time (when it would switch from ground to air)
  - Own/lease own plane? Hire own pilots?
    - Most primarily charter
    - 9 OPO's owned planes (not specifically owned by OPO)
      - 0 owned jets
      - Pilots were contracted
      - 6 OPOs hired their own pilots
  - Availability of charters
    - Use of charter brokers (Brokering for planes)
    - Benefits OPO's but must be specific

- Organs vs. people
  - Staff 2 pilots

- **Group 2: Delays**
  - Main themes
    - Safety issues from delays
    - Surgeon availability
    - Donor OR times (ramifications) - donor instability/loss of organs
    - Recipient impact (Instability of recipient)
    - Donor OR time limitations (ramifications with relationships with other donor hospitals)
    - Donor consent
    - Compliance (expediting allocations)
    - Pilot availability (timeout and unavailability)
    - Intraoperative declines
    - Commercial flight availabilities
  - Solutions
    - Brokerage (so everyone is aware of availability)
    - Use of Drones
      - Currently - there are drones being used to transport (possible to deliver organs in the future?)
    - OPO based surgeons vs. everyone flying in and out
  - Comments: Building these tactics into limiting factors

- **Group 3: Costs**
  - Average - $15-20k
  - Owning plane vs. chartered
  - OPOs not really knowing the costs (people interviewed possibly did not have data or did not know?)
    - Absorbed by transplant center most times (big center would be able to absorb this better than a small, rural center)
    - Cost report available? - reaching out to transplant administrator committee for report (for transport and Medicare %)?
      - How do you write this up? This is something to think about, not a recommendation as a guidance document is concerned.
      - There should be a regular review of standard acquisition costs
      - CMS - are they aware of these plans? These costs would affect them (Susan will look into who is the right person to connect with)
      - Salaries of pilots going up which would affect costs for OPO's
      - Recovery surgeon locally
      - X-matching (variability) and virtual x-matching
  - Ground transport cheaper
  - Helicopters (most OPO's do not use)
  - "On Call" fee

- **Group 4: Distance & Future Plans**
  - Able to increase access?
    - Overall concern for charter availability
    - Concerns: talking to correct people or people assuming not a real issue
    - Should OPO and transplant program come up with an accreditation component to address safety issue

- Lung change experience?
  - Cost of OR is per minute
  - Impacts relationships with donor hospitals
  - OR time delays and impact on families (if there are delays, there can be a risk of losing donor families)
- Broader Sharing challenges
  - More complicated: allocation, coordination, OPO resources being increased
  - Potential donor loss
  - Adding more pilots and planes
  - Evaluating staffing models

- **Group 5: Relationships/Streamlining Communication**
  - Refusal codes: meaningless and do not lend themselves to current system utilizing those codes; does not reflect credibility
  - Build into template an introduction section
  - Focus on staff: utilization of staff and the impact of that
    - Utilization of surgeons from transplant centers and those going into retirement
  - Recovery surgeon malpractice programs - if they are working for another hospital, are they covered?
    - Reporting damage
  - Payment practices
    - Consistent payment practices and models for reimbursement
  - Transporting fewer staff
    - OPOs working together to provide services for each other
  - Lack of availability of data
  - Metrics
    - Mortality rates and discard rates
  - Comments:
    - Variations of payments
      - Some go to surgeons, some is absorbed to transplant center
      - No consideration for what the surgeon might be doing
      - Must incentivize surgeons to have it done locally

- **Group 6: Organ Allocation Procedures**
  - How to allocate to back up patients
    - Target list: patients at each transplant facilities that would be "easy" to transplant
      - HLA lab Is central and can be managed centrally
      - Aggressively respond to backup placements
    - Setting OR time
      - Lot of power setting OR time (can have huge impacts)
        - Remind people of guiding principles of OR Time setting
    - Specimen sharing and cross matching (virtual)
      - Virtual cross matching
        - No consistency around to do this
        - Some level you will need to have the capability to do this
        - HLA lab perspective - tied to your own local transplant center (CMS dictates these agreements)
      - Specimen sharing

- Limited amount of specimens
  - Labs can say they don't have the resources that are needed which should prompt them to build those systems to support these factors
  - Encourage more liberal use of cross matching
    - Antigens and FMI
    - Inconsistent standards across the country on what is considered positive
    - Add in a layer of consistency to build a level of confidence in testing
  - Transplant labs share specimens that cross match upfront which is a good idea to foster

Next steps:

- All notes will be consolidated into an executive summary.
- Each committee member will write three sentences that correspond with their assigned sections.
- Drafted sections will be sent to the Committee Vice Chair by November 6th
- Deadline for guidance document to make spring public comment: December 14th
- Public Comment for guidance document: January 22 – March 22, 2019
- After public comment, the committee will review the public comments, revise the guidance document as needed, and will present to the board in June.

7. Patient Safety Data

UNOS staff provided an overview of the updated patient safety report. The data discussed was from January – June 2018.

Summary of discussion:

The patient safety report is updated twice a year. Highlights of the report include the following:

- Self-Reported Patient Safety Events, 2018
  - 121 reported patient safety events
  - 53 (43.8%) were self-reported safety events

- Patient Safety Cases by Event Type:
  - The top four cases reported were:
    - Transplant Procedure/Process (18%)
    - Living Donor Event (18%)
    - Communication (12.4%)
    - Testing (9.1%)

Table 2. Living Donor Events

Events	N	%
Aborted procedure	13	72.2%
Death	3	16.7%
Redirection	1	5.6%
Other	1	5.6%
Total	18	100.0%

Out of 18 total responses, 13 (72.2%) reported aborted procedure as their primary event.

Table 3. Transplant Procedure/Process Related Events

Events	N	%
Other	14	73.7%
Sterile Field breach	2	10.5%
Donor/recipient compatibility check not performed	1	5.3%
Vessels used in a non-transplant patient	1	5.3%
Equipment malfunction	1	5.3%
Total	19	100.0%

Of the 19 events that were sub-categorized as other, 13 were related to storage of prohibited vessels.

Table 4. Communication Events

Events	N	%
Change in test results not reported	4	26.7%
Inaccurate/insufficient donor or (organ/extra vessels) information	3	20.0%
Increased risk status of donor	3	20.0%
Other	3	20.0%
Missing documentation	1	6.7%
Misinterpretation of test results	1	6.7%
Total	15	100.0%

This table shows the reported events related to communication. Out of 15 reported events, the primary event reported at n=4 (26.7%) was change in test results not being reported. The secondary events reported, each with n=3 (20.0%) were inaccurate/insufficient donor or (organ/extra vessels) information, increased risk status of donor, and other.

Table 5. Testing events

Events	N	%
ABO- Other	4	36.4%
HLA- Inaccurate results reported	2	18.2%
Infectious Disease- Hemodilution error or discrepancy	2	18.2%
ABO- error or discrepancy	1	9.1%
Other Issue (Not Related to ABO, HLA, Infectious Disease)	1	9.1%
ABO- subtyping error or discrepancy	1	9.1%
Total	11	100.0%

Of the 11 testing related events, ABO (Other) events were the most common at n=4. Of these, 3 were recipients who were re-listed in Waitlist with a different ABO than a prior listing.

A Committee member asked if the results were on the instances where the person was re-listed were corrected on the second submission (second person verified patient information and realized it was different from what was initially entered). UNOS staff stated that these occurrences are in

relation to cases where someone was transplanted 15-20 years ago with an ABO and now are re-listed with a different ABO. Another committee member inquired about how many of the results reflect pediatric who were then listed as adults. UNOS staff noted that it is believed that not many reports meet this scenario.

- ○ **Discard of Organ**
  - ○ Primary events include:
    - ▪ Communication
    - ▪ Recovery Procedure/Process
    - ▪ Transportation

- ○ **Delay of Organ**
  - ○ Transportation rated the highest for the primary reason for delay

A Committee member commented that this report represented a very small subset of cases. The Committee acknowledged that there is probably under reporting because it is voluntary. Since there is no mandatory reporting of adverse events, it poses the question of whether transplant programs should have their own systems in place, regardless of whether they report to UNOS or not. A Committee member stated that they perform internal case reviews at her center and such systems are in place for adverse events as required by the Centers of Medicare and Medicaid Services (CMS) regulations. It is believed that while self-reporting is encouraged, the challenge is to avoid being too punitive in order to yield a richer data source.

The Committee Chair inquired about an update regarding vessels and the prohibition of storage of Hepatitis C positive vessels. He noted that with the increase of Hepatitis C liver transplants there might be a need for Hepatitis C vessels. UNOS staff stated this topic can be added to a future conference call agenda and identified as a project idea.

Next steps:

A Committee member recommended comparing trends over the years for the next patient safety report update. Another Committee member made a suggestion to add site survey data to the patient safety report.

8. Other Significant Items

UNOS staff shared various updates with committee members. Updates included:

- **TransNet Update**
  - ○ Android data loss (fixed)
    - • Activity became intermittent on the OPO side resulting in data loss. This problem has since been resolved.
    - • New feature set is being worked on: Living donor functionality
      - ▪ There is a trend being observed where OPOs are packaging and labeling more of living donor organs
      - ▪ In mobile application (Nov. 7), living donor organs will be able to be labeled and packaged with the app
      - ▪ Extra validation (for living donor cases) is required to ensure correct laterality verification
      - ▪ New miscellaneous package labeling (free text)
  - ○ New supported technology
    - • Support for Apple and Android updates

- New printers with better hardware to improve connectivity within the operating room

The Committee Vice Chair asked if there was any progress being made to allow TransNet[sm] more accessible on iPhones (rather than iPads). UNOS staff responded that there is progress being made but were unable to estimate when it will be available for iPhones. They also noted that it would be a 4-5 month effort with complete redesign of the app.

Another Committee member commented on the living donor labeling on TransNet and wanted to know if this also allows the capability to check in these organs with the same barcode scanning as with deceased donor organs. UNOS staff clarified that this should work in TransNet; the manual enter donor ID would still work. UNOS staff agreed to make this information is correct. A Committee member commented that the only difference with using TransNet entirely for living donor organs is the verification requirements. UNOS staff replied that this is accurate and is an issue that remains a challenge. The pre-organ arrival verification presents a gap and there is work being done on including this in programming to enable this feature in TransNet.

Another Committee member questioned how the living donor functionality would impact the OPO's security in order for transplant centers to pull out that functionality in TIEDI[1]. Additionally, will there be help documentation for the OPOs so they will be able to work with their transplant centers to set this up. UNOS staff responded that as long as the transplant center is with the OPO's DSA, they can pull information manually into TransNet at any time.

- **Extra vessels projec**t
  - Internal project meeting is underway
    - Mobile side – programming should begin in the next couple of weeks
  - Website may not kick off until January (there is a halt in this project with the web team due to obligations with liver committee)
  - Plan to deliver this all by June 1, 2019
  - Features and functionalities
    - New deceased and living donor vessels label
    - Labels have been approved to the printer
  - Production - Q2 2019
    - There will be a lot of communication and education up until a month before going live

A committee member recommended that an update on the extra vessels project be provided to the OPO Executive Directors during their meeting in January 2019.

- **Post- Recover Test Results Timeline**
  The Committee Vice Chair discussed the background information about this project. Six years ago, UNOS and many committees did a failure mode analysis on post-recovery results process. They found several failure modes in that process that could lead to transplant programs not receiving results that could allow them to effectively treat their patients. The

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[1] Transplant Information Electronic Data Interchange

idea is to communicate and acknowledge receipt of test results through DonorNet. The current updates of this project are as follows:

- ○ This is an advocacy project that is a joint effort with the UNOS IT/Customer Services team. UNOS staff noted that the IT/Customer Services team handles IT projects that come from members
- ○ This project does not have a strict deadline

The Committee members agreed that this is a good idea and will make the process more efficient. The Committee Vice Chair commented that there will need to be systems in place to streamline this process and that it will need to start out as a pilot in order to evaluate and develop this project. There are 5 OPOs that have agreed to be part of this pilot.

- **Histocompatibility HLA data project**
  - ○ Having data going from a reader machine straight to UNet
  - ○ The Committee is supportive but unable to work on this project at this time due to other IT commitments at this time.
  - ○ There is a 3-6 waiting period and will be reevaluated in January/February 2019
  - ○ The technology already exists where it is set up that OPOs can receive HLA results electronically.
    - ▪ There will be some HLA labs used to pilot this project

The Committee Vice Chair suggested that the issue of DonorNet labels not matching the labels produced by HLA labs be addressed as part of this project. One Committee member stated this is potentially a complex discussion that will need to be part of the project development process.

- **Proposed CMS Transplant Program Conditions of Participation (COP)**
  - ○ The Transplant Administrators Committee (TAC) has been involved in these discussions.
    - The TAC plan to provide comments to the Executive Committee
    - The TAC comments will be sent to the OSC to review

UNOS staff provided an opportunity for committee members to provide comments. One Committee member suggested the following:
- ○ Use this as an opportunity to provide feedback on how there are redundancies in regulations and member reviews.

Upcoming Meeting
- November 29, 2018 (Teleconference)