OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

OPTN Operations and Safety Committee
In-Person Meeting Minutes
March 28, 2019
Chicago, IL

Michael Marvin, M.D., Chair
Christopher Curran, CPTC, CPTBS, CTOP, Vice Chair

Introduction

The Operations and Safety Committee met in Chicago, IL on 3/28/2019 to discuss the following agenda items:

1. Guidance on Effective Practices in Broader Distribution
2. Methodology for Identifying Transplant System Level Features
3. ABO Project
4. Project Updates: DonorNet® Functionality, Human Leukocyte Antigen (HLA) Interface, Post Recovery Test Results Sharing Project
5. Research Update: Patient Safety Report and Policy Monitoring Reports
6. IT Updates: Extra Vessels, Split Liver Label
7. Other Significant Items

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

1. Guidance on Effective Practices in Broader Distribution

Committee Leadership provided an update of the Committee's proposed guidance document, the public comment responses and discussed next steps of the proposal process.

Summary of discussion:

The Vice Chair provided an overview of the Committee's guidance document and the public comment responses. Overall, there was support for the guidance document. There was opposition from Organ Procurement Organizations (OPOs) and the Association of Organ Procurement Organizations (AOPO) specifically related to the financial aspects of the guidance document. It was voiced that the discussion on the finances of organ recovery, organ procurement, and how those costs were determined, was beyond the purview of the OPTN.

There was a question raised by the American Society of Transplantation (AST) about one particular line in the histocompatibility section about relying more on virtual crossmatching and whether or not that statement conflicted with *OPTN Policy 4.6: Crossmatching*. The Committee reviewed the current policy language and agreed that there is a lot of variability around what constitutes the final crossmatch. The Vice Chair clarified that the recommendation in the document states there should be greater reliance on virtual crossmatch. The intent of the section was to provide guidance for when a specimen is being shared from one OPO to a transplant program. Currently, OPOs share specimens with transplant programs when time allows and when a patient needs a crossmatch but even today, transplant programs are encouraged to do virtual crossmatching before a specimen is sent on a plane. The Committee agreed that the section does not state exemption from physical crossmatches and decided to keep the section as written.

The guidance document was presented to the Committee to review and discuss the revised sections of the guidance document. The first six sections were not changed except for minor edits. In response to the public comment response, the Organ Recovery/Surgeon Billing section of the guidance document was removed and revised to provide guidance on suggesting that

there was transparent communication between OPOs and the recovery team for this process. UNOS staff consulted with the Organ Procurement Organization (OPO) Committee Leadership to ensure that this was an appropriate revision within the guidance document and was told the revisions were acceptable.

Another member asked if these changes still provided the information that the guidance document intended which is to raise awareness to address the issue? The Vice Chair stated that there are many variant practices and there should be communication between OPOs and transplant programs of what their expectations are without being prescriptive. The proposed revisions meets those needs. The Committee Chair stated that this is something that should be addressed because there will be more local surgeons recovering with broader organ distribution. If the surgeon is not recovering for their own program, there should be some agreement in advance. Although it is beyond the purview of the Committee to state what that agreement should be, it is believed to be acceptable to provide guidance stating that there should be transparent communication between the two organizations.

A member stated that from feedback received, there has been concern voiced that guidance documents are routinely used to develop into policy. Another member asked if there are time intervals and if this conversation should be done in advance to doing the recovery since there is no suggestion of this in the guidance document. A member stated that this would begin to be prescriptive in the guidance document, which can teeter into writing policy in a guidance document.

The member continued by asking if the guidance document is trying to state that there should be a conversation or if OPOs and transplant programs should discuss the reimbursement piece as these are two separate issues. There are other mechanisms that cover the financial side that are beyond the purview of the OPTN. If the intent is to get OPOs and transplant programs to have a conversation, the guidance document can get to the conversation without mention of the reimbursement piece as there is common knowledge about this already.

The Vice Chair clarified that not everyone is aware of the reimbursement piece because of the variance among OPOs and transplant programs. There should be something in the document to provide recommendations. It is recommended that there should be an understanding or conversation between the OPO and the recovery team. Ideally, this conversation would be before the recovery takes place rather than afterwards but it is beyond the scope of the Committee to mandate this. The revisions are purposely vague while also saying that the OPOs, transplant surgeon and transplant programs should have a dialogue about their expectations.

A member stated that it seemed odd to state what should be included in the invoices. The Vice Chair stated that there are many instances where invoices are sent and no information is provided. This information is intended to make billing more streamlined. The Committee decided to remove the sentence regarding what should be included in invoices. A member suggested that this information could be included in an educational piece about effective practices that is less prescriptive if there is found to be a need.

The Committee Chair stated that these conversations have to happen and should be written down. A member stated that there needs to be an intentional conversation. The role of this Committee and the guidance document is just to provide guidance. The name of the section may not need to be billing and instead is more of a guidance of administrative processes. The Committee agreed to delete the billing title and including one point to the previous section.

A member suggested to send a note to the ASTS to recommend that these conversations are done. Health Resources and Services Administration (HRSA) staff clarified that it would not be appropriate to send a recommendation to the ASTS on behalf of the OPTN Operations and

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Safety Committee as it would be coming from the OPTN. It was recommended that members could reach out to the ASTS individually (separate from the committee) as representatives of their respective programs.

A member suggested that in the "Establishing the Time of Organ Recovery", section of the guidance document, donor families should be listed first. The sentence was edited as suggested.

The Vice Chair moved for a vote on the revised guidance document and the Committee unanimously approved the revised guidance document to be considered for Board approval.

Vote: Approve: 14, Oppose 0, Abstain 0

Data Collection Project

The feedback question on whether or not there should be data collection related to transportation was received with support during public comment. Members reviewed the following suggested data elements for initial data collection:

- Type of transportation used (fly vs. drive, multiple modes)
- How specifically was the organ transported (chartered plane vs. commercial flight)
- Who recovered the organ? (local surgeon)
- Distance traveled
- Time (hours) between transport of the organ to when organ was transplanted

The Vice Chair asked UNOS staff on clarification on whether there was data already being collecting on who recovers the organ. UNOS staff clarified that there is some data collected but this data is not reliable for use.

The Vice Chair continued that this data collection would preferably be long term and would be collected using a form that is currently in use, such as the Donor Organ Disposition Form or Deceased Donor Registration Form. The use of these forms would require Office of Management and Budget (OMB) approval.

A member stated that the Data Advisory Committee (DAC) was working on a data collection project to update the OMB forms. UNOS staff stated they will follow up with DAC to determine the status of their data collection project. If they are working on a project already, the Committee can incorporate their data elements into their project. Otherwise, the Committee can continue with their proposed data collection project.

The Committee Chair stated that one of the biggest effects of broader sharing is delay from the time that all the organs are placed and accepted and the time when the donor is actually placed in the operating room. This is an important data element to track – what kind of delays do we have due to broader sharing?

The Vice Chair stated that there are a number of things that are currently being tracked in a different way that OPOs are looking at individually that are not specific to allocation such as time of consent to recovery, and time of brain death declaration to recovery.

The Committee Chair replied that the time when all organs are allocated is a critical data element. Although there may be some delays due to placing lungs, but this is not necessarily related to broader distribution. Once all organs are being accepted, the timeline begins and it would be interesting to see if this could be tracked. A member stated that there should be some kind of assessment of other negative consequences of broader distribution, besides time and costs. The Vice Chair clarified that this is so variable that there are certain milestones that should be looked at to collect more information.

The Committee Chair asked if there was any data collected in regards to this instance where an organ is offered and then rescinded. A member clarified that this would be considered a decline and would be documented as such in the system. Another member stated that this was one of the concerns that some OPOs had. If there were delays because of the change in allocation with broader distribution, how much of an impact will this be on the donor families? The Vice Chair stated that there is a risk of losing organs but this is not new. This may be impacted by broader distribution but it is on an individual organ level that this should be looked into.

A member suggested measuring allocation off the match. If there was a case where the organ was not able to be transplanted due to time restriction, it would be recorded as "Organ not recovered" on the disposition report. There is a new field in DonorNet that OPOs are using which can allow observations of when donors are going to the OR, and measuring the time of the final acceptance for every organ.

The Committee Chair asked if it was standard practice for OPOs to convert the time from organ placed to organ placed prior to the OR. It is not believed that this is what happens. The Vice Chair stated that the data fields with tentative OR times is not very reliable. Broad milestones should be looked at that are already collected. There are other data elements in addition to what is being suggested that are already being collected that can be used to monitor this such as brain death time and recovery time.

UNOS staff clarified that the goal of this project is to introduce data elements that are not currently being used to collect data to assess logistical impacts of broader distribution.

The Committee Chair agreed that chartered plane vs. commercial flight is an easy data element that should be collected. The Vice Chair stated that for every organ, there can be multiple legs of travel that can require different modes of transportation. How these different modes are tracked will be important.

The Committee Chair asked if there would be a caveat to be used in determining if the information provided is standard operating procedures or if it is due to broader distribution. A member reminded the committee that the OMB process renews every three years. By the time that this form is updated, the old allocation will now be the new allocation.

HRSA staff clarified that there will be new forms with DonorNet, which will be one new package. There will still be the three year rotation, but it has been discussed going forward that if there are new changes and it is keeping up with the new policy cycles, the OMB process would begin as the policy changes are being worked on. There would be change memos developed so if there is a new change, there is not a delay in implementing these changes.

UNOS staff suggested that it should be considered that this might be a broader discussion including other stakeholders. There should also be a conversation with DAC to get further clarification of their data project before moving forward.

The Committee agreed with this.

Next steps:

- UNOS staff will follow up with DAC to get further clarification on their data collection project and discuss the Committee's proposed project to determine next steps for the Committee

2. Methodology for Identifying Transplant System Level Features

UNOS staff provided the Committee with an overview of the Organizational Excellence plan to Identify Transplant System Level Features.

<u>Summary of discussion:</u>

UNOS staff provided an overview of the objectives of the Organizational Excellence team which is to provide support on proactive identification and addressing safety events.

A member stated that previously, this type of culture of safety was presented and there was some unease in presenting and publishing some of the data that was collected. As this project is taken on by the committee, the member wanted to make sure that there was buy in from other partners, namely HRSA and the Membership and Professional Standards Committee (MPSC). HRSA staff asked for clarification from the member on their statement. The member clarified that there is a pushback in terms of putting language in documents that are publically available about what the goals would be that could potentially be punitive or regulated. HRSA staff stated that in watching how things are moving within HRSA and MPSC becoming more of a member quality perspective, there is more support toward this culture of safety. Through efforts like the Collaborative Innovation and Improvement Network (COIIN) and other items, it is moving towards being non-punitive. HRSA would support any efforts being made to use what is learned in confidentiality to educate the community. When it gets to small numbers where events can specifically be identified, HRSA would work with the Committee on this.

The Vice Chair stated that a culture of reporting that is non-punitive would make this an easier process. Using these lessons learned in real tangible ways would make this effective. It would also be very valuable to work with other Committees, HRSA and UNOS staff to address these issues. HRSA staff agreed with this and stated that it would be a good learning experience for their team as well.

The Vice Chair asked if there was an opportunity to enable the people who are reporting and willing to share their stories to do so. There are members who are willing to discuss what has happened and what they've learned so that everyone else can avoid it but there are other bodies that are preventing them from discussing these incidents. The Committee Chair provided an example of the ABO project the Committee is currently working on. The level is so high on privacy that there are challenges in how best to address these issues.

A member stated that most of the quality discussion is protected under patient safety work product. This allows for really robust quality discussions in a protected environment. When this information begins to be reported, this interferes with the processes that are already in place to discuss this in confidence.

UNOS staff stated that this conversation presents a great opportunity for broader conversation to create a blameless environment, which would result in better reporting to be able to identify opportunities for improvement. It is an important conversation that will need to continue to move forward. Another approach could be the proactive approach of looking at key processes and identifying those failure gaps. UNOS staff asked members what their experiences were in safety culture learnings.

A member stated that their organization's goal has started with education and trying to change the culture. The first step is to educate the providers of what patient safety really is and what approaches that entails in reporting errors. There are no incentives to report but the goal is made clear that the more reporting that is done, the more processes will improve.

Another member stated that previously, their organization takes the content from their quality discussion. By removing patient information from their data, they are able to lead on the discussion of the problem and detaching the information from the patient. UNOS staff stated that this approach would be in the same manner where the focus would be just on the process versus the individual event.

UNOS staff stated that the goal of the project would be to provide an analysis that focused on some key processes that would result in a mitigation of those processes. UNOS staff will serve as a resource they noted that this would not need to go through the process of the Policy Oversight Committee (POC).

The Committee Chair stated that every aspect of broader distribution would be great for this process, it would help in the facilitation of communication between the programs for organ allocation. The Vice Chair added that efficiency in the organ allocation process should be monitored.

A member stated that risk assessment would be a great topic to address. Waitlist management is key for transplanting acceptable candidates. Some waitlists are long, especially with kidney allocation. Another member stated that the danger for transplant programs that have a large wait list and can also disenfranchise candidates. There are assumptions made that are not correct.

The Vice Chair stated that through the days of donor management, there needs to be a way to monitor that key elements are transitioned among the team efficiently. How are handoffs done from one surgeon to the next? How is this communication process done more effectively? A member stated that there are different types of equipment, processes and names used. With broader distribution and the use of other surgeons traveling to procure organs, it may be more efficient to standardize practices. The Committee Chair agreed with this and stated that standardization of the recovery process should be looked into further.

UNOS staff proposed that the Committee prioritize one or two key areas of focus to begin. The goal would be to have some information to share and discuss during the fall in-person committee meeting. It is the goal that from the information collected, there can be guidelines made by the Committee.

A member stated that the education would get simpler if the patient safety subject matter expert (SME) within organizations could be used as a resource. UNOS staff agreed with this and stated that they would select patient safety SME's based on information recorded in the system database. There will be a stakeholder group that will be developed.

A member suggested that it would be helpful if each member could identify 1-2 points that are being experienced. Although it would be helpful having patient safety SME's join the

HRSA staff asked what things can be included in this process that can feed into this process well. The Committee Chair stated that this is a question that members should think about and can be brought up in discussion during the next Committee meeting.

Next steps:

- Committee members will identify 2-3 focus points, which will be shared with the UNOS Organizational Excellence team to begin the project

3. ABO Project

The Vice Chair provided an update on the Committee's current ABO project.

Summary of discussion:

The Vice Chair provided an overview of the ABO events and the project that has been developed. A project form was submitted to the POC. The feedback from the POC was that it was a valuable project but there needed to be more direction and plan on what the project will be.

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An ABO Workgroup was formed that included a collaboration between the Operations and Safety Committee, members of the Organ Procurement Organization Committee, as well as blood bank and histocompatibility SMEs. The first meeting was held on March 7, 2019, where the workgroup established the following goals:

- Identify alternative methods of ABO typing, including availability and accuracy
- Create an awareness of the impact massive transfusions can have on blood type determination
- Protocols and definitions
- Identify time between blood samples, amount of transfusion, and size of the donor that impact a donor returning to their actual blood type
- Education for the community in whatever form the workgroup determines will be the most effective
- Guidance and further defining massive transfusions – indeterminate results and conflicting results
- Has there been any type of change within trauma hospital protocols related to massive blood transfusions

The workgroup discussed focusing the project on providing education to the community, but there is a possibility to review current policy language as well. The Committee Chair stated that this would be an educational effort, as there are many parts of this process where it is not common knowledge among the community.

The Vice Chair continued by reviewing a recent letter from the MPSC that provided recommendations for the Committee to consider in addressing ABO issues. The MPSC recommended that the Committee take a holistic approach and not limit the focus on massive transfusions. There was agreement that the transplant community would benefit from education and guidance regarding why blood type determination may be difficult or inaccurate, ways to prevent it, and how to address indeterminate blood type results.

The Committee Chair and Vice Chair stated that the letter was helpful. The Committee Chair suggested that when the Committee's project in addressing ABO issues, it should be published in one of the transplant journals. The Committee was appreciative of the suggestions shared by the MPSC.

The Vice Chair stated that next steps would be to address the additional recommendations provided by the MPSC. The Vice Chair workgroup will also recommend to revise some of the policy language to address next steps if there are discrepant test results. It is anticipated that the project's educational and proposed policy revisions will be included in the spring 2020 public comment cycle. The Committee members agreed with this plan.

Next steps:

- Workgroup calls will be held monthly (first Thursday of every month)
- Once a plan has been developed, the project will be resubmitted to the POC

4. Project Updates: DonorNet Functionality, Human Leukocyte Antigen (HLA) Interface, Post Recovery Test Results Sharing Project

UNOS staff provided the Committee with an update of the DonorNet Functionality, Human Leukocyte Antigen (HLA) Interface, and Post Recovery Test Results Sharing Projects.

DonorNet Functionality

The Committee Chair provided an update of the DonorNet Functionality. This functionality would allow the ability to communicate in an automated fashion to provide real time updates during an

organ recovery while in the OR. There was a Customer Advocacy meeting where Committee Leadership presented this information to UNOS IT staff. Currently, the project is on hold due to the volume of prioritized requests from IT. The Vice Chair added that this project was well received during the Customer Advocacy meeting. The feedback that was given was that the current tool that is available has not been widely used so far and that this would need to be utilized for further evaluation.

Human Leukocyte Antigen (HLA) Interface

The Committee Chair provided an overview of the HLA interface project. Currently, HLA data is entered manually and this creates opportunity for errors. An IT service request has been submitted and the next steps will be to include Histocompatibility Committee leadership to the conversation. IT will determine the resources needed based on the information provided from that discussion.

A member asked if they will be looking at other systems besides DonorNet where HLA data is entered. The Committee Chair stated that the gold standard would be to completely automate the entry of HLA data.

Post Recovery Test Results Sharing Project

The Vice Chair provided members with a summary of the post recovery test results sharing project. Currently, there is a disjointed process for reporting post recovery test results. This project will allow the ability to enter this information into DonorNet and transmit to transplant centers that have received an organ from those donors and alerting them that there is new information available. This process will allow for a streamlined, consistent approach where if there is information needed, there will be one place to get this information. There are five OPOs and transplant programs that are participating in the initial pilot.

The Committee Chair asked about the positive or negative results. The Vice Chair stated that this information recorded pertains to positive results or negative results that end up being positive. This is a communication tool and it is the hope that this will become an automated communication.

A member asked how the notification will be sent. The Vice Chair stated that the notification would be an e-mail sent to either the patient safety contact or to the person on-call for the transplant program. The Vice Chair confirmed that this notification would be an e-mail notification with the ability to click on it and acknowledge that the information was seen. The OPO would be notified whether the notification was acknowledged or not.

Another member stated that an advantage to this would be that the information provided would be more efficient and gives the ability to check this information in a more filtered way. The Vice Chair added that with broader distribution, it will provide more streamlined communication with other programs.

5. Research Update: Patient Safety Report and Policy Monitoring Reports

UNOS research staff provided the Committee with an update of the Patient Safety Report and Policy Monitoring Reports.

Summary of discussion:

UNOS staff provided the Committee with an update of the Patient Safety Report data.

Patient Safety Report

The data covered safety situations reported to Incident Handling from January 2016 – December 2018. In general, the trends are the same as far as proportions but generally, the number of cases are decreasing.

The Committee Chair asked if this was a reflection of actual data decrease or lack of personnel. UNOS staff clarified that the decrease is accounted by the vessel sharing cases, which are no longer reviewed by the MPSC. The Ad Hoc Disease Transmission Advisory Committee (DTAC) data is not included in the data provided. A member stated that a lot of this information comes from the data portal. The Vice Chair asked if this information comes from audits and UNOS staff clarified that none of this information comes from site survey visits.

UNOS staff continued by reviewing data of patient safety cases by reporting type. The transplant centers accounted for the most cases by reporting type followed by other, and then OPO. A member asked that when an OPO and transplant center enter the same event, would this count as two events or one. UNOS staff clarified that this would only count as one event.

UNOS staff continued that there has been a slight decrease in self report patient safety events from 46.6% in 2017 to 43.5% in 2018. UNOS staff then discussed the patient safety cases by event type. Among the reported events, transplant procedure process is the most frequently occurring case reported. It is believed that this is due to extra vessel sharing. The Committee Chair commented that data entry error is being demonstrated as decreasing. It would appear that members are beginning to fix these problems since not much data is being entered anymore. The Vice Chair stated that without understanding what each of the categories represent, it is hard to know what the Committee should focus on. For example, when looking at data entry, it does not specify exactly what the actual issue is. Should trends be observed to determine what the issues are?

A member asked what the category of "Other" represented. There was a 5% increase that was observed. UNOS staff explained that there has been an increase in general program complaints such as surgical coverage or general patient outcomes and it is believed that this has accounted for the increase in this category.

The Vice Chair asked that without looking at the specifics of the cases, are these cases tracked in a way where if there was an increase that is of concern, it would be presented to a Committee for something to be done.

A member asked that in looking at the living donor data, is there anything other than the deaths that are observed? The Committee Chair stated that this could be presented as a standard – whenever this type of data is presented, there should be a look into the details going forward of the living donor data. UNOS staff stated that for subcategorization of the living donor event, 70% of the data in 2018 represented aborted procedures.

The Committee Chair stated that the question would then be why these procedures were aborted. UNOS staff confirmed that all living donor events (all aborted procedures, redirections, and deaths) are reviewed by the MPSC. If there are any trends, it is discussed, but there would not be a way to identify specifics of the incidents. A member stated that the Committee has been tasked with observing trends and the details of the events. This has been the approach of the Committee and has been how the information was presented to them previously.

Another member stated that it is interesting to look at the communication errors. Were the communication errors within a program, between OPOs and transplant programs? Moving forward, this would be more important to determine what can be learned from those.

A member commented that when looking at quality of rare events –looking at the data at this matter does not show the number of data being used and getting an understanding of the scale of the event. The Committee Chair stated that the number being presented is fairly small. Other than aborted procedures and death, what is also in this number? UNOS staff stated that the living donor data includes aborted procedures or death, native organ failure, other, and non-utilization. A member stated that this data should be looked into further. For example, why were there aborted procedures? Although the numbers presented are small, there is clearly a three point trend showing an increase in aborted procedures.

The Committee Chair suggested that the Committee continue to monitor this data and added that the interesting points to review for 2019 would be travel and communication due to broader distribution.

UNOS staff continued by showing a table highlighting communication events. The top two events in 2018 were change in test results not reported and inaccurate/insufficient donor information. The Committee Chair stated that the 0% of delayed reporting might imply that there is significant underreporting. The Vice Chair asked members if there were other particular events that should require a submission in policy. There are probably a lot of events that are unknown because they are not required to be reported. One of the things in this field should be required reporting. The Vice Chair asked if there are other high level/high stakes events that should be reported. UNOS staff were asked if there were any anecdotes from the data that has been reviewed. UNOS staff replied that there is nothing that has come up right away and that they would need to come back to the Committee after thinking about this question.

UNOS staff shared the Transplant Procedure/Process Related Events. The Committee Chair highlighted the vessels used in a non-transplant patient had virtually been eliminated. A member stated that this is due to this information being mandated now. The Committee Chair asked for clarification on if Hepatitis C vessels are recovered and destroyed immediately (never stored), would they need to be reported? The Vice Chair stated that they were asked by DTAC if this should be a reconsideration of the ability to store Hepatitis C positive vessels.

HRSA staff replied that this should be discussed further with DTAC. At a patient safety standpoint, the labeling has improved, but there is always a concern that errors are still possible. The Vice Chair stated that there should be an upcoming conversation.

UNOS staff continued with reviewing the Transplant Procedure/Process Related Events table and pointed out that the "other" category was in relation to storage of prohibited vessels. The Vice Chair asked for clarification on if it was self-reported that the vessels were stored. UNOS staff confirmed that this information was self-reported. The Vice Chair asked what the trigger was for this. Was the disposition not marked within a certain time in a Hepatitis C donor? UNOS staff clarified that it would be marked as stored and then once the extra vessels are discarded, this triggers the report. A member asked if this information was validated in site survey. Another member agreed that this was the case.

UNOS staff reviewed the sub-categories of the Testing Events data. The top event was the drop off in infectious disease, which dropped to 8% in 2018. The Committee Chair commented that the numbers in the data are very small.

UNOS staff continued with reviewing the event impacts on any organs. There was an increase in non-recovery organs. From 2016, there were 8.1% non-recovery organs. This increased to 12.6% in 2018. A member asked if this meant there were about 25 organs that were non-recovery. UNOS staff stated that this was correct – 25 of the events reported resulted in an organ not being recovered.

The Committee Chair commented on the decreased rate of delays but that it would be expected to increase. UNOS staff was asked about details on the increased rates in discards from 2017 to 2018. UNOS staff replied that there was not enough information to identify a trend, but it can be attributed to a variation of circumstances such as surgical damage that wasn't identified or reported at the time of acceptance, delays, inadequate preservation, and transportation.

A member stated that previously, the Committee focused on the sub-categorization, which helped to identify and focus efforts on the extra vessels labels. The challenge is that now three years out, with a change in the system, there is an attempt in trying to determine the most effective way in reporting and looking at the data.

A member asked if UNOS staff could provide some more granular detail on the living donor aborted events. UNOS staff clarified that they would look into this information further to share with the Committee.

Another member suggested some focus also being on the packaging, shipping and transportation events as well. It was acknowledged that there is not mandatory reporting when it comes to these events, can there be some conclusions drawn that the Committee can address?

Extra Vessel Policy Monitoring Reports

UNOS staff provided members with an overview of the Extra Vessel Policy Monitoring Reports. This report was in response to the extra vessels policy and monitoring extra vessel usage since implementation.

The extra vessel disposition data from January 1, 2016 – December 31, 2018 showed no changes during that time. Over 70% of all extra vessels were observed to being destroyed during this timeframe. In 2018, there was 8.5% of vessel usage reported at the time of waitlist removal.

UNOS staff then reviewed the HCV, HBV, or HIV Positive Vessels by disposition. Over the years, there was an increase in the number of properly disposed vessels. In 2016, there was a high number of policy violations which decreased in 2017 and 2018. In looking at late reporting and storage, the extra vessel disposition reported more than seven days from transplant/destruction date, there was a decrease. In 2018, there was an increase but towards the end of 2018, a decrease began to be observed. For extra vessels stored more than 14 days from recovery date, there was a steady decrease with a spike shown in the last quarter of 2017, and then decreased and stabilized in 2018.

UNOS staff continued with showing members data representing primary vs. secondary recipients. The vast majority of the transplants were primary recipients. The next set of data demonstrated the distribution of storage interval for vessels transplanted into secondary recipients in 2018. From previous reports, the data has not changed much with the median number of days being six days between recovery and transplant for secondary recipients. The Public Health Service (PHS) increased risk of vessels used in secondary recipients was shown to steadily increase, with the biggest increase being from 14.3% in 2017 to 18.1% in 2018. A member asked for clarification on what this data meant. UNOS staff clarified that this meant that in 2018, there was 18.1% of all extra vessels that were used in secondary recipients are PHS increase risk.

UNOS staff summarized that there were similar trends in extra vessel reporting across the years of 2016-2018. There was a 25% relative decrease in vessels reported late from 2016- 2017. There was a 16% relative decrease in vessels reported late from 2017 – 2018. There was an increased use of PHS Increased Risk vessels in secondary recipients in 2018 and an increase in proper disposal HCV, HBV, or HIV positive vessels year over year.

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UNOS staff showed additional data from the data report that came from a data request a year ago regarding extra vessel usage from living donors. The vast majority of transplanted vessels are used from deceased donor transplants. Around 13-18% are used in living donor transplants. There was only one case where an extra vessel from a living donor was recovered and used in a transplant. Over all three years, there are seven reported instances of extra vessels being recovered from living donors with one case where the extra vessels were used in transplant.

ABO Evaluation

This report covers from July 1, 2016 – December 31, 2018. There are three high level patient safety event categories: data entry, labeling and testing.

- Data Entry Issues: There were 71 patient safety issues related to data entry. Only four of these cases were related to ABO issues, all of which were waitlist related
- Labeling Issues: There were 50 patient safety issues related to labeling. Thirteen events were sub-categorized as blood/nodes/spleen labeling issues. Three events were related to ABO
- Testing issues: There were 63 patient safety issues related to testing. Fifteen events were related to ABO testing issues. There were ten events sub-categorized as "other" ABO related events, eight of which were related to discrepant results from previous listing

UNOS staff continued with a review of data regarding recipients not on the match run. There were 153 cases identified where 85.6% of the cases were directed donation. A member asked what all other cases were classified as. UNOS staff clarified that there were a variety of reasons, but they were believed to be from exhausted lists, which were intentional and not based on an error.

The Vice Chair stated in the past, there was a discussion about putting the ABO compatible at the end of the list. It was vehemently discouraged because it lengthens the list and significantly slows down the process of organ placement.

The Committee Chair asked if blood compatible blood types being at the end of the lists should be looked at again. The Vice Chair stated that there was a discussion regarding this with MPSC as a concern and at the time OPOs were encouraged to develop a verification process. Most of the directed donation requests end up not going through due to incompatibility.

A member stated that the majority of the directed donations pertain to two programs. It was suggested to discuss the processes they use and discuss lessons learned. UNOS staff stated that from ABO, there was a request to program a living donor verification in UNet which would be in Waitlist and TIEDI. It was on the list for programming, but every time this has been placed on the list, it has been deprioritized. The Vice Chair stated that theoretically, it could follow the same process as directed donation. UNOS confirmed that this was correct because every candidate must be on waitlist. The Vice Chair stated that the only thing that exists in policy is in the Final Rule where there is a prioritization for directed donation. There is no policy around the process where programs are trying to come up with systems that are safe and are widely variable from one OPO to another.

The Vice Chair stated that there could be some guidance on this process as it is not consistent from one OPO to another from how it is handled. UNOS staff clarified that in terms of the transplant program perspective, there is a policy that requires them to do this on their end.

A member stated that the policy language is much different. Previously, there was not any policy language for OPOs as it related to directed donation. There is now some language pertaining to

this, but the language is not specific. The Organ Center used to provide guidance in the past on how to manage the directed donations. The Vice Chair stated that there are other components that are not considered, such as how social media impacts this and other confidentiality components that come up. A member agreed that this would be a good area for guidance.

UNOS staff continued with a review of data pertaining to candidate and donor ABO discrepancies. The Committee Chair remarked that the numbers presented were small, which is a good indication that it validates the importance of double entry. A member confirmed that a transplant candidate cannot be entered on the list until the second entry is entered. UNOS staff clarified that one of the data requests from a previous meeting was to try and identify where in the process these mistakes were getting caught. This information is in the report, but essentially, this information is not kept. All that can be seen is that whoever put in the initial entry, can go back and change that information.

UNOS staff continued with data representing deceased donor ABO discrepancies. There were 311 of 26,087 deceased donors recovered with ABO changed between initial and secondary verification. Among those cases, 69 were considered significant discrepancies. UNOS staff reviewed data regarding duplicate donor entries. UNOS staff clarified that this data was only looked at from the donor side. If there are errors in the double entry, a new donor form is created to enter the data correctly. Duplicate donor information is self-reported where that information can be compared. The audit tables show the same numbers. There is no capability to determine when ABO typing errors are caught during the double verification process.

A member asked what would happen if both entries were found to be incorrect – if the test results are verified as one blood type and then it is discovered that it is actually a different blood type, would a new candidate registration need to be created if there is an error in the double verification? Another member stated that this information is unable to be modified. This information would require going through the Help Desk to resolve the issue.

The Vice Chair asked if there was a process where the help desk could unlock the form, make it blank and then allow members to go through the data entry process again. UNOS staff stated that it is most likely something that would have to be mediated by the Help Desk but would reach out to get more information on how this information is handled.

The Committee Chair asked members if they would like to look into this further. A member voiced interest in knowing more information on the recipient end. The Committee agreed.

6. IT Updates: Extra Vessels, Split Liver Label

UNOS staff provided the Committee with an update of the extra vessels and split liver labels.

<u>Extra Vessels</u>

UNOS staff provided an update on the extra vessels project. There is both a policy and programming aspect to this project. The policy defining extra vessels as organs as well as reporting of the sharing of extra vessels went into effect on March 1, 2019. The programming to accommodate the other policy changes is under development with an effective date that is unknown at this time.

UNOS staff provided members with a demonstration of the revised vessel labels. The infectious disease test results section of the label now only includes 8 infectious disease tests (it previously listed 14 infectious disease test results). Unknown is no longer an option in reporting these test results. The options that are available now match DonorNet. Previously, the options that were required to report did not match DonorNet, which caused confusion among staff and members. The label is being more explicit with policy requirements and outlining when the extra

vessels can and cannot be stored. The new labels are expected to be available in stores in a couple of weeks.

UNOS staff continued by demonstrating the extra vessels label with TransNet^{sm}. At the top of the label, it shows the storage date for the extra vessels, which will only be printed if the extra vessels can be stored. The storage date will be automatically calculated 14 days post-recovery so that there will be less confusion in how to count the 14 days. For the infectious disease portion of the label, Anti-HBc has been changed (formerly Anti-HBc Ab) as well as the HIV Ag/Ab Combo (formerly HIV Ag/Ab Combo Assay). UNOS staff showed a mockup of the infectious diseases screen in the TransNet application. The infectious disease results are in the same order on the screen as they are on the label. The Vice Chair asked if this differs from the screen that shows all of the serology results. UNOS staff stated that serology results are not collected in TransNet. The full list of infectious disease test is available in DonorNet.

UNOS staff continued with a discussion on the Donor Organ Disposition Report. There was a policy request for OPOs to view extra vessels disposition reported from a transplant program. If there is disease transmission recognized late after transplant or procurement, the OPOs currently do not have an effective method to track who received all of the extra vessels that were procured from the donor. It was determined that the best solution was to create a new table in the Donor Organ Disposition Report to include extra vessels. It highlights some of the donor information, the match ID, transplant center who received it, and if extra vessels were sent. This would allow OPOs to track the vessel disposition.

The Vice Chair stated that the feedback form is required to be completed within five days and that after that time, the information is not usually reviewed. He asked if there was any thought about how this would be posted on the transplant center side? It also does not allow the ability to enter information when vessels are recovered separately to go to a transplant program for the purpose of a living donor procedure. Is there a thought that this would be showing on the transplant center side when vessels are sent alone? UNOS staff stated that it would be the transplant program that would report this disposition. A member clarified that this is manually entered on the transplant program side.

UNOS Staff noted that a number of OPOs were contacted to gain insight on how they track vessels. They all use their electronic donor records for this type of tracking and communication of who receives the vessels. Members were asked for clarification on this. A member stated that this has not yet been solved in the electronic donor records. OPOs are able to determine where the vessels were shipped but are unable to determine the outcome of the vessels. The OPOs have no way to know unless they receive a notification of the outcome. The only information the OPOs can see in the DDR is whether or not the vessels were used in the procedure. The request would be a way to see a disposition of the extra vessels. It is currently on a form that the OPOs typically do not look at after the completion of documentation after five days.

A member stated that typically when reporting to a liver center, OPOs are waiting to hear back from the transplant programs to determine the outcome of the organ. UNOS staff stated that business architects for DonorNet should be included in the conversation at a future Committee call to discuss this further. The member continued that the architecture doesn't have to be changed – it would be helpful just to be able to print out an extra vessel report from the OPO side.

UNOS staff stated that this information could be placed on TIEDI. If there was an extra vessels report, it would just include a status update. A member noted that the request from the OPOs would be the ability to run a report to see the vessels that are associated with their donors.

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UNOS staff asked if there should be any specific permissions to access this information. The member stated that this would be a perfect use of this security check. It was suggested to follow the same permission as the OPO report that is in TIEDI. UNOS staff stated that there will be additional mock ups and changes that will later be presented to the committee.

<u>Split Liver Labels</u>

The Vice Chair provided an update on the split liver labels. There was a request to mock up a label to indicate right and left segments of livers so that the laterality of the liver segments are labeled accurately. Currently, there is one standard label used where the laterality is written in. It is the intent that when packaging the organs, the surgeon would be able to identify the laterality easier.

A member stated that left and right should be aligned with segment 1 and segment 2. The definition for segment 1 and 2 have nothing to do with left and right. This can be done without modification of DonorNet, but there should be standardized language where this can be deciphered.

The Vice Chair stated that this can safely be labeled left and right. A member agreed with this and stated that this would just need to match with the terminology currently in use.

<u>Next steps:</u>

- Extra Vessels: UNOS staff will continue to do additional mockups and changes, which will be presented later to the Committee for further discussion.

7. Other Significant Items

<u>Critical Comments to Health and Human Services (HHS) Regarding Liver Policy</u>

The Vice Chair reviewed the recent critical comments that were sent to HHS regarding liver policy. The letter requests suspension of the policy approved in December 2018.

A member stated that this is a contentious issue especially when you disadvantage patients. For example, candidates who reside in more rural places. This has been a discussion during regional meetings.

Another member stated that it would be a good idea to discuss whether the current definition of PHS increased risk still makes sense or if this should be standardized. HRSA stated that federal stakeholders have been discussing this at a very high level. The Committee would be included, but since it is a federal document, a discussion will first need to occur with the federal partners.

UNOS staff added an updated that a notice went out from UNOS communication last night to all liver programs and OPO staff to inform the community about the NLRB being implemented on April 30, 2019, along with the liver distribution.

The meeting was adjourned.

Upcoming Meetings

- April 25, 2019 (Teleconference)
- May 23, 2019 (Teleconference)
- June 27, 2019 (Teleconference)