OPTN/UNOS Operations and Safety Committee Meeting Minutes November 29, 2018 Conference Call

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

Introduction

The Operations and Safety Committee (OSC) met via teleconference on November 29, 2018 to discuss the following agenda items:

- 1. Project Updates
- 2. Proposed DonorNet® Communication Plan
- 3. HLA Initiative

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

1. Project Updates

The Committee Chair provided an update to members on current Committee projects and deadlines.

Summary of discussion:

Travel Questionnaire

The Committee Chair provided an update on the travel questionnaire that the Committee completed per the request of the Ad Hoc Geography Committee. The Committee completed and sent a report summarizing the results of the questionnaire and recommendations, to the Geography Committee, which was added to the materials for the December 3-4, 2018 Board of Directors meeting. There is a scheduled vote on liver allocation policies at the meeting and it is anticipated that a focus on kidney allocation changes will follow. Now that the travel questionnaire has been completed, the Committee will be focusing on the completion of the effective practices guidance document.

The Committee Vice Chair provided an update on the progress of the effective practices guidance document.

Guidance Document Update

The Vice Chair asked for feedback from the Committee Chair on incorporating a section in the guidance document regarding guidance for OPOs and transplant centers building their resources for broader geographic distribution. The Committee Chair agreed that there could be a section that can work some of the data from the questionnaire in a format that can work as an outline of the guidance document providing some of the questions/concern from the questionnaire and including potential planning on what may be needed (delays, pilots timing out, etc). It was agreed that this would be built into the guidance document. The goal was to have a Committee vote during the 11/29 meeting but this has been delayed. UNOS staff clarified the timeline in voting for the document would need to occur during the 12/6 Committee call or the 12/13 Committee conference call. The Committee was updated on the following deadlines for the Spring 2019 public comment proposals:

- Draft Public Comment Proposals: December 14, 2018
- Public Comment: January 22- March 22, 2019

Board Meeting/Board Approval: June 2019

A member asked if any additional help was needed to complete the document in time. The Vice Chair assured members that progress is being made but there were some delays due to other subcommittee projects as well as the holidays. The document is coming together now and it is expected that it will be completed within the next two weeks, at which time the Committee will vote on the document.

Next Steps:

The final draft of the guidance document will be completed and voted on by Thursday, December 13, 2018 during the Committee's scheduled conference call.

2. Proposed DonorNet Communication Plan

The Committee Chair and UNOS IT staff discussed a proposed DonorNet Communication Plan. The Committee Chair provided background information on a proposed collaborative effort between the Committee and UNOS IT staff to streamline communication during the allocation processes.

Summary of discussion:

The Committee Chair provided background information about the idea behind the communication plan. The Committee Chair noted that the current way of communicating updates during allocation process is outdated and time consuming. The current process involves constant phone calls between the host OPO and the transplant coordinator on the status that then gets relayed to the transplant surgeon. He noted that there should be a more effective way to streamline this communication. The thought behind the proposed communication plan is that there should be a way where the coordinator on site in the OR has a way of communicating when the patient gets in the operating room, when the incision is made, when cross clamp occurs, when the organ is packaged, and when the organ leaves the donor facility. On the receiving end, the user would be able to look at this information through a text message or e-mail, or however the user choses to customize their alerts. In its simplest form, if a transplant hospital is receiving an organ, they should be able to log into DonorNet and look at the information.

A member stated that they believed this would be a great idea, especially in the middle of the night when people are getting these notifications. The member asked if this plan would is contingent on TransNetsm programming. The thought that in knowing that OPO coordinators on site use TransNet to package the organs, it may be an easy way to get information into DonorNet. Ultimately, this is a question that would be referred to IT in deciding if this is a reasonable option.

The member stated that this would be at the hands of the recovering hospital initiating this process. Patients go to the OR and you can look at the monitor to see where they are in hospitals so it seems to be something that should be able to happen. The Committee Chair clarified that the coordinator from the host OPO on site in the OR would be providing updates in real time. The donor/coordinator on site is usually the one who calls or communicates information to the host OPO call center because typically the call (from outside hospitals) isn't going directly to the OR; they are calling the host OPO at their call center who then communicates with the coordinator on site. The idea is that this mechanism may also be able to communicate to the host OPO call center; just one message that goes to everyone at the same time. Potentially, it would reduce the number of phone calls and streamline OPOs ability to get the work done efficiently.

A member inquired whether the backup to this plan would be to revert back to what is normally done (making phone calls) in the event that there were connectivity issues with TransNet. The Committee Chair confirmed that this would be the backup plan and that there should always be someone available in the case that something happens and a phone call needed to be made.

Another member stated that this would be a good idea but had a few comments regarding the proposal. The member commented that setting the OR date for OPOs often times doesn't even happen – sometimes transplant hospitals will receive a call after an organ has been out for a period of time and being asked if they are interested in accepting the offer. The member commented that their OPO puts OR time estimates in the donor highlights section in DonorNet. While this isn't always completely accurate, it does provide the transplant center with an estimate of when the organs might be allocated or procured. The Committee Chair agreed this would give the opportunity to enter the information directly from the OR or within the call center.

UNOS IT staff provided some background information on the functionality that was put into DonorNet back in early 2017. This functionality was one of the innovation projects that added the ability for OPOs to notify transplant centers of the OR time. This was one of the first basic attempts to look at the ability for OPOs and transplant centers to start sharing information via email or text message directly from DonorNet and having members subscribe or unsubscribe to receiving alerts. The idea was that in starting with OR time, it could gauge how the community was using the functionality and being able to expand that functionality to other things such as cross clamp or sharing pertinent information that the community felt was important. The biggest issue since the implementation of this functionality is that there hasn't been a lot of adoption. It is uncertain if this is due to the fact that there are issues with it or that members are unaware that the features exist.

UNOS staff demonstrated the functionality as it looks on DonorNet. The demonstration showed the view and functionality from the perspective of an OPO. Any user who has access to the donor record (including the transplant center users) has the ability to follow the donor. Currently, there is an ability to select the OR date as tentative or scheduled as well as the recovery facility. The recovery facility could be categorized as the donor hospital or customized if an alternate facility is being used. That information is then saved in the DonorNet record.

The Vice Chair asked for clarification that if someone is following a particular donor and the OPO updates information, will this change be automatically sent as an alert, or does the OPO have to update the information and send an alert. UNOS staff stated that after an update is made, no alerts get sent until a user clicks the "send alert" button to actually send another alert to everyone who is following the donor.

UNOS staff demonstrated how transplant staff can follow a donor by choosing an option (e-mail or SMS text) to receive alerts. The follow donor feature is available to both OPO and transplant center staff who have read access to a donor. Once an OPO has an OR date and time set, the OPO can send an alert. A donor summary alert will be shown so the OPO can view the users that received the alert. UNOS staff also noted that there is a feature where the user can unfollow the donor.

A member asked if the alert to users include any changes that have been made to the donor's record, even if there are multiple changes at different times. UNOS staff stated that the alert just sends the data as it is in the donor record at the time of the alert. If there are any changes made and an alert was sent again after that change, it will only show the updated data at that time.

A member commented that this would be a great concept if it were more widely known by the transplant community. There should be a way to automate the alerts for certain data points that can be sent directly to the on-call staff or anyone who is following the donor. It would be ideal to

have the flexibility for some data to be automated as well as some that are optional based on the user's preference. UNOS staff stated that this is a function that is already built with the hopes of having more users adopt the functionality. There is a one pager that will be sent to the Committee that provides more information about the functionality and how it works. Members were encouraged to send this information to their staff to increase the awareness of the functionality and help in promoting the adoption of the functionality.

A member asked if there was any automated data sharing between TransNet and DonorNet. The things that are being done in the OR in TransNet are critical time points and it would be helpful if they could be automatically updated into DonorNet. UNOS IT staff stated that this is something that could be incorporated but they would like to see adoption of the current functionality before adding additional notifications. UNOS staff asked for feedback on the best way to get more information out to the community to ensure that what is being built is what members want and that there is an awareness of what is being added to the system.

The Committee Chair commented that the issue with the current functionality is that being able to know the time that the OR is set is not enough information to be helpful. Other information as previously discussed, such as patient in the room, incision time, cross clamp time, and packaging time are also useful information for transplant center staff. The Committee Chair asked if there was a way to have access to DonorNet in a timely fashion so the information can be entered. A member stated that this depends on the particular hospital. If there is good internet connectivity, there probably isn't an issue. The other issue would be that it is easier if only one or two organs are involved as opposed to a seven organ donor with numerous people in the OR trying to manage the case.

The Committee Chair commented that typically it is easy to send a quick text message. It is believed that it may be easiest to have a text messaging capability where some type of automated message can be sent when a donor is in the room. This could also be within TransNet or some application that can be preloaded with the donor information and have the capability to send an alert in the same manner.

Members agreed that this was a worthwhile project to pursue. UNOS staff clarified that this project would not be associated with any type of policy but agreed to clarify this with leadership. Generally, when there is a request that is not associated with policy, it goes through the customer advocacy pathway. As a committee, if it is decided that it is a priority and members want to place a request to work on this project, it can be submitted through the IT intake process and it will get prioritized.

The Chair asked IT staff for confirmation on UNOS IT staff being willing to work on if the committee could get approval. UNOS IT staff confirmed that this would be a project their team would work with the committee on. However, the process for prioritizing these projects is different than for Board approved policy proposals. Following Board approval of policy changes, there is a guarantee that within 12 months it would be programmed. This timeline does not apply for non-policy projects and there is the potential that IT staff may not be able to work on this project for some time. The Chair agreed to this point and stated understanding to the fact that that given everything going on with organ allocation.

The Chair noted that the Operations and Safety Committee has done a lot of the work that was done prior to the questionnaire has been asked of the committee rather than the committee asking of others. UNOS staff agreed that this has been the case and understands the committee's desire in being proactive with this focus being on the operations side of making things more effective and efficient. The Chair agreed and stated that in considering the increase of inter-OPO communication with broader sharing, streamlining communication would be very

helpful and timely in that regard. UNOS staff stated that some kind of recommendation in reference to this could be added at the end of the guidance document.

The Chair asked for next steps to move the request forward. UNOS staff stated that an intake form would need to be submitted. This intake form would be completed and submitted by UNOS staff on behalf of the committee. IT staff would reach out to the committee to work through the requirements and determine the level of effort. This would then be moved forward and put through the customer council and subsequently prioritized.

Next steps:

Completion and submission of intake form by UNOS staff.

3. HLA Initiative

The Committee discussed a proposal that would provide the ability for HLA typing software to directly upload results into DonorNet so that it does not get entered manually.

Summary of discussion:

The Committee Chair asked when the initiative would be going into effect. UNOS staff clarified that this has not gone into effect yet because it hasn't been approved by the Board of Directors. It is on the consent agenda and will likely be approved in December 2018. It will require programming, which will happen within 12 months following Board approval. With the other organ allocation policy changes, it is unknown at this time where the HLA initiative will fall within the programming schedule. When there are policies that are approved and they require IT, there is a system notice sent out 30 days before it goes into effect. The Chair stated that it looks like the double entry proposal will be approved by the Board of Directors and it would make sense to try to determine the best way to operationalize the interface between HLA typing software and DonorNet to reduce human error that occurs with manually entering all of the data points.

A member stated that it was hard to believe this is the still the current process for HLA typing. The Chair agreed that it is interesting how the Committee spent an extensive amount of time on ABO verification, where the chances of having a problem are rare and remote, and yet all of the HLA typing is entered manually which could lead to errors that cause organ rejections and graft loss. A member noted that most of the time it is done correctly but it is surprising to know that there is a system in place that allows for the manual entry of this type of data.

The Vice Chair asked for clarification on if this electronic version would be available for both unacceptable and donor HLA or if this discussion is just around donor HLA. The Chair clarified that this should include everything. It is the thought that since there are not many HLA typing machines (the actual hardware that does this), the hardware should be able to communicate directly into DonorNet. It was discovered that there is some work that would be required from the HLA directors and technicians where they would have to look at the programs directly and make decisions and then put it into the software. The Chair also stated that this initiative is important enough not to just be a suggestion – it should be mandated if it can work. Committee members agreed with this.

A member inquired if this initiative being mandated would require software companies to work with UNOS to build the interface. The mandate would be that the software be compatible with DonorNet. The Chair stated that this would be something that the software companies would typically be fine with working on. There would obviously be a cost and the hospitals would have to work with the specific software company to determine how much it would cost.

Next steps:

Histo proposal (on the consent agenda) will be voted on during Board Meeting

Upcoming Meeting

• December 13, 2018 (Teleconference)