OPTN/UNOS Operations and Safety Committee
Meeting Minutes
January 3, 2019
Conference Call

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

Introduction

The Operations and Safety Committee (OSC) met via teleconference on January 3, 2019 to discuss the following agenda items:

1. Feedback Question for Public Comment
2. Update and Discussion: ABO
3. Additional Discussion

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

1. Feedback Question for Public Comment

The Committee discussed and voted on whether or not to include a proposed feedback question for public comment regarding support for additional data collection.

Summary of discussion:

The Committee Chair provided a brief summary of previous discussions regarding the inclusion of a feedback question asking for more data collection to analyze the logistical aspects of broader distribution.

A member stated that it would make sense in general to get more data and asked what the downside would be in making the request. The Committee Chair clarified that the question is intended to get a sense from the community if they would support data collection efforts to support future analysis and policy development. The Committee members agreed there was no downside to asking the question. UNOS staff agreed with this and stated that part of the discussion would be how much data would be needed, who would collect it, and what would be the minimal burden for the gain (in broader sharing). With all of the current allocation changes, one of the biggest concerns voiced by the community was increased flying and logistical challenges. One Committee member voiced support for collecting additional data as long as it does not create an undue burden on members, in particular OPOs.

Another member asked if it was worth including the type of data to be collected. The Committee Chair agreed that the committee could provide a series of questions to use in data gathering and include this in the public comment document for feedback. A member voiced uncertainty on the ability to gather data now since there is currently no source for baseline data. Another member commented that the questions would be asking for ongoing collection of data because it is thought it would change as allocation changes. Even without a baseline, it could be useful for evaluating trends.

A member asked if data would also be collected by the Ad Hoc Geography Committee. The Vice Chair clarified that the Geography Committee was tasked with putting together expectations, but would not continue as a committee after establishing the frameworks for broader distribution. The Committee Chair stated that UNOS should be collecting data to analyze what happens after broader distribution proposals are implemented. UNOS staff clarified that every policy is evaluated at specific time points post-implementation.

One Committee member voiced support and stated that it would make sense to ask the question of whether or not the community feels there is value in collecting this data. The Committee could then use the feedback to determine the logistics for the data collection. The Chair asked members if they supported including the proposed feedback question in the public comment proposal. The members unanimously supported this.

2. Update and Discussion: ABO

UNOS staff provided information about discussions that have occurred since the previous conference call. This included the recent member notification, recent events related to ABO, and a review of the recent member questions around clarification on ABO policies and procedures.

Summary of discussion:

UNOS staff provided an overview of the notification that was sent to members on November 30, 2018. This communication was a patient safety notice regarding the importance of using pre-red blood cell transfusion blood samples for ABO typing. It was recommended that if such a sample is not available, members should consult with blood bank experts or other experts on the best approach to getting accurate blood type results.

UNOS staff then discussed the increase in member questions about ABO typing that have been received within the last month. Topics included:

- Documentation (when receiving differing blood type results)
- Testing methods
- Additional testing after inconclusive results

The Committee discussed some of these member questions. There were some questions about whether or not there were two genomic results prior to listing (since two ABO results are required). When consulting with the blood center, they questioned the need for a second test, which caused some confusion. The Committee Chair asked what sample was used (buccal swab, blood sample, etc.). The member clarified that a blood sample was used for the genomic testing and there was no blood transfusion. The member commented that when getting inconclusive results, it is not clear what needs to be done. There was a generic response from UNOS which prompted the center to decide on doing two tests. The member noted that when they consulted with the blood center, two tests were not recommended.

The Committee Chair stated that in discussions with the Chair of the Histocompatibility Committee at the recent Board meeting, it was mentioned that HLA labs were capable of doing buccal swabs and that the timeframe for getting results is comparable to other testing. A member stated that their program has used buccal swabs for some of their testing for HLA and it took approximately 4-6 hours to receive results. The Committee Chair asked members if most HLA lab had the capability of using buccal swabs for testing. One member stated that this is dependent on the individual labs capability to perform such testing.

The Committee Chair reminded the members of a previous discussion to consult with subject matter experts, including blood bank experts, as the Committee moves forward with the ABO discussions. A member stated that there is a blood bank pathologist that helped the Committee previously and offered to forward this information to UNOS staff. The Committee Chair agreed to reach out to recommended experts and invite them as consultants to committee meetings.

UNOS staff then provided information on the number of donors that received blood transfusions prior to recovery. Between October 2008 and September 2018, approximately 4,000 out of 88,000 donors received over 10 units of blood before organs were recovered. The data does not provide information about whether or not pre-red blood cells transfusion specimens were available.

UNOS staff provided information about the subtyping guidance which states that any amount of red blood cell transfusion could potentially impact the subtyping results. This might also impact the primary ABO results, although there is currently no guidance directed to primary typing.

UNOS staff provided a review of current OPTN policy, which requires OPOs, recovery hospitals, and transplant hospitals to have and follow protocol when there are conflicting results for primary blood type. The only information currently available is in regards to subtyping, which recommends consulting with the blood bank expert.

UNOS staff provided an overview of previous ABO work done by the Committee. When the Committee worked on the ABO policy changes five years ago, they conducted a detailed Failure Modes and Effects Analysis (FMEA). This resulted in the identification of over 60 failure points. The top 10 failure points were highlighted and shared with members and included "No pre-transfusion specimen is available for testing" as the number 5 failure point. At the time, the Committee did not feel that OPOs had a lot of control over this because by the time they take over donor management, blood transfusions may have already been given. One solution that was put forward was to always check with the blood bank on the availability of any pre-red blood cell specimens and use it for blood type testing.

The Committee Chair asked members for their feedback on what they would want to know and what should be done to address ABO issues. A member stated that these instances happen so infrequently that it would be helpful to have some guidance about what should be included in the protocols that the hospitals and programs are expected to develop. The Vice Chair agreed with this and stated that it would be helpful to get input from blood bank experts about additional testing methods that could be introduced. The Committee Chair stated that this could potentially be included in a guidance document.

The Committee discussed the next steps to address the ABO issue. One member agreed with the plan to develop a guidance document. The Committee had previous discussions about this with one of the big problems being the inability to mandate one specific methodology over another. A member noted that it would be helpful, certainly from the OPO perspective, if there could be some guidance on a more accurate methodology.

UNOS staff agreed that guidance and education was a good approach. It will allow the Committee to have a firm foundation about what has changed since some of the policies were developed and implemented. It was suggested that before the next scheduled meeting, the recommended experts should be contacted to see if they would be willing to provide a 15-20 minute presentation. UNOS staff performed a literature search which would be provided to members for their review.

This concluded the agenda discussion items.

Next Steps:

- Subject matter experts will be invited to participate in future discussions.

3. Additional Discussion

The Committee Chair provided a few project reminders and updates.

Summary of discussion:

The Committee Chair reminded members of the projects that have previously been discussed. The first project was to propose streamlining communication between OPOs and transplant programs. The hope is that this project can be continued through the IT Customer Advocacy pathway since it is not a policy project.

The Committee Chair continued with the second proposed project of creating an interface between HLA software and DonorNet. This project would address patient safety and automate the way HLA data is entered into DonorNet®. Some members still manually enter this information. The Committee Chair asked about the status of the double entry policy developed by the Histocompatibility Committee. UNOS staff noted that this policy was approved by the Board of Directors in December 2018 but has not been programmed yet. The Committee Chair stated that since it was approved, it might be good timing to add the interface as well. It was agreed to add this topic for the next meeting agenda to discuss with IT in further detail. UNOS staff mentioned that the goal is to have all UNet℠ data being shared electronically without any manual entry and is a high priority for the UNOS IT department.

Next Steps:

- Interface between HLA software and DonorNet project will be placed as an agenda item for the committee's next scheduled meeting.

Upcoming Meetings

- January 24, 2019 (Teleconference)
- February 28, 2019 (Teleconference)