OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

OPTN Operations and Safety Committee
Meeting Minutes
April 25, 2019
Teleconference

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

Introduction

The Operations and Safety Committee met via teleconference on April 25, 2019 to discuss the following agenda items:

1. HLA Initiative
2. OE Proactive Analysis Project
3. ABO Project Update
4. Data Collection Project Update
5. Extra Vessels Update
6. Miscellaneous

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

1. HLA Initiative

The Histocompatability Committee (Histo Committee) Chair discussed the logistics of the proposed HLA interface initiative.

Summary of discussion:

The Histocompatability Committee (Histo Committee) Chair began the discussion by providing members with background information on the Histo Committee. One of the roles the Histo Committee has been tasked by the Board is to monitor HLA discrepancies. Every quarter, the Histo Committee look at the typing that was entered into the database and compare it to either the donor or recipient histocompatibility forms for TIEDI. Since the end of 2014, the critical errors (defined as those that had a potential impact on allocation) have had a consistent error rate of 2%. In 2017, a letter was sent to all HLA laboratory directors and supervisors to look into their discrepancy rates to identify any trends and review their processes if needed. There are still a series of errors present. The Histo Committee addressed this issue to the board on their initiative to double entry. Currently, the initiative is in programming in IT and is expected to be implemented at the ending of the year.

The Histo Committee leadership recently discussed with the Operations and Safety Committee leadership to eliminate the entry and make a process where the data could automatically be uploaded from the laboratories' database into UNet. There was some identified challenges of being able to upload data directly into UNet. There are two main software programs that are in place for HLA software, but not all of the labs in the United States have these programs. Many laboratories have their own programs or do not use a program at all. There is not a standard format.

The Histo Committee Chair continued by adding that another idea that was discussed was having the data uploaded directly into UNet from the programmers where the laboratories get the typing. There are some different options available to establish this procedure, but it will take some time to determine the best mechanisms to achieve this goal.

The Vice Chair asked that when talking about critical errors that impact match runs, how many are are attributed to administrative vs. discrepant typing between two labs. The Histo Committee Chair stated that there is probably 50% entry errors or clerical types of errors but it is almost impossible to determine. In the majority of the cases observed, there was indication that the member went back in and made another match run, demonstrating the potential to impact allocation.

The Vice Chair continued by asking what the error rate of entry of candidate HLA. The Histo Committee Chair stated that this information was unknown. It is mandated to have double checks of HLA typing. Evey laboratory is required to go in and double check HLA entry of their candidates at some point in time.

A member asked if the administrative errors were from HLA or OPO staff. The Histo Committee Chair replied that 70% of the errors were made by the HLA laboratory. The member continued by asking if there was a way of interfacing programs directly into the system, would this remove any review from directors? The Histo Committee Chair stated that for some programs, a double verification system is required for electronic transfer data. If the data is directly downloaded from a program and it gives an allele level typing, this would have to be entered into UNet to change this information to an equivalent. There may be another layer of changing and double entry in that respect. The Histo Commttee Chair commented that it may be better to go from the software program, where the data has already been verified, and then directly upload this information into UNet. The Histo Committee Chair reiterated that there are some laboratories that do not have software, but there could be a standard format (such as Excel) that could be utilized and then upload into UNet.

Another member asked that when looking at the errors, did the Histo Committee have any concerns with the virtual crossmatches? The Histo Committee Chair stated that there was no way of knowing which laboratories are performing virtual crossmatches or when virtual crossmatches have been performed. UNOS does not capture this data.

The Vice Chair asked how the new policy that is currently being programmed will impact the Operations and Safety Committee's proposed HLA initiative. The Histo Committee Chair stated that the new policy would have an impact for clerical errors that are being made. It will not take care of the interpretive types of discrepancies.

The Vice Chair continued by asking if there was an HLA specific allele that tends to be more problematic. The Histo Committee Chair stated that when looking at allele level errors, most problematic cases are associated with parents and splits. Education is provided in response to these errors. All of the results that are reviewed are blinded so it is unclear which laboratories are making the errors. There may need to be more education for those types of errors.

The Vice Chair summarized the Committee's plan to gather stakeholders to develop a subcommittee and work on a project plan to submit to the Policy Oversight Committee (POC). The key is to develop requirements that any member can meet by still meeting the goal of data being electronically entered.

There were no further comments or questions.

2. OE Proactive Analysis Project

UNOS staff reviewed and discussed the Organizational Excellence (OE) Proactive Analysis project and the Committee's role.

Summary of discussion:

UNOS staff provided members with an overview of the Organizational Excellence (OE) Proactive Analysis project. UNOS staff recently presented the project proposal during the Committee's in-person meeting. The goal of the project is to help the Committee identify potential failure modes and determine how to potentially address performance action plans to prevent the failure modes from happening. The project emphasis on a more proactive process as opposed to a reactive process. UNOS staff have worked internally to identify a proactive safety analysis process and provided Committee leadership with a letter including a one page summary of the project to review and send to the Committee.

The Vice Chair comfirmed that the recruitment letter had been received but had not been sent out yet. The Committee plan to provide UNOS staff with feedback in response to the letter. The Vice Chair asked if the recruitment pertained to Committee members or quality staff to engage in the process. UNOS staff clarified that the recruitment would involved both Committee members as well as members of their quality staff at their facilities who they identify.

UNOS staff summarized the content of the letter which is asking members to join one of two subcommittees that are going to look at two areas the Committee has identified as focal points for this process: recovery practices and waitlist management. There was a work plan put together for the two processes which will work consecutively for a span of nine weeks. There is a time commitment of 12 hours which will be a combination of five meetings totaling 8 hours and four hours of offline work. The offline work would allow members the opportunity to review the work that has been done and provide feedback to the rest of the Committee to push the process forward.

UNOS staff continued by providing members with an estimated timeline for the project:

- May 27 – August 2: First analysis
- August 5 – August 9: Internal review
- August 12 – October 4: Second iteration of project
- October 24: UNOS staff will present project results during Committee in-person meeting

UNOS staff continued by explaining to members that the intended goal was to have about 10-12 members serve in each subcommittee.

The Vice Chair asked if members would be able to include subject matter experts (SMEs) who are not a part of the committee but would be valuable to the processes of the project. UNOS staff stated that the decision would be at the discretion of the Committee members. The OE team's role is to help facilitate the process. In terms of the content, failure modes, and identifying opportunities for action would be coming from the members of the Committee.

There were no further comments or questions.

Next Steps:

- Committee leadership will send the recruitment letter to members.
- Members will provide feedback and identify additional recruits for the project.

3. ABO Project Update

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

Summary of discussion:

The Vice Chair provided an update on the Committee's current ABO project. The workgroup is still educating themselves on the issues surrounding the project. One of the blood bank SME's that has been recruited for the workgroup will give a presentation on the various ABO

technologies that are available for circumstances where donor ABO is either in question or alternative methods are needed. The workgroup will also look further into donor transfusion.

The Committee will begin to update the ABO project form for resubmission to the POC.

There were no further comments of questions.

4. Data Collection Project Update

UNOS staff provided an update on the Committee's proposed data collection project.

Summary of discussion:

UNOS staff began by providing some background information on the Committee's proposed data collection project. During the Committee's in-person meeting, it was discussed that during the public comment cycle, there was a feedback question regarding data collection for modes of transportation and logistical impacts of broader distribution. There was initially some confusion on whether DAC was working on a similar project. After an internal meeting, it was determined that DAC was not working on a similar project and the Committee was told to move forward with the proposed project.

UNOS staff has worked with Committee leadership to complete the project form for the proposed project which was submitted to POC staff for review. Committee leadership has also worked with UNOS staff to draft a letter to send to organ specific committees, the Data Advisory Committee (DAC) and Transplant Advisory Committee (TAC) to see if they had any recommendations for inclusion in the project form.

The POC will vote on the project form during their in-person meeting in May. The public comment proposal will then be completed for submission in late June.

There were no further comments or questions.

5. Extra Vessels Update

UNOS staff provided the Committee with an update on the Extra Vessels project.

Summary of discussion:

UNOS staff provided the Committee with an update on the Extra Vessels project. The development of the project is well underway with an expectation of a late summer release for the first phase. There are some changes included in this process before implementation. There will be various forms of communications and educational efforts within the next few months in the forms of e-newsletters, tech news, and e-mail blasts in an effort to reach out to all users.

The first set of changes that members are familiar with is the removal of the unknown result option from the PHS increased risk question in DonorNet and TIEDI. This is important because if users have unknown results for infectious disease tests at the time of a match run, it can potentially impact the match run. Members will be instructed to stop using unknown result options.

There will also be instruction on what to select in different scenarios. For instance, if the coordinator is unfamiliar if the infectious disease test has been run or not, they are selecting "unknown" when it actually should be pending. If the infectious disease test has been run but the results are not back yet, members are being instructed to list it as pending and not unknown. If coordinators are unsure if a test is run, they should be marking it as "not done". If the results are inconclusive, the coordinator should mark the test as "indeterminate". These should ensure that the match run is not impacted.

The Vice Chair asked if there would be any communications going out to address results that are equivocal, which is a result that is in a lot of infectious disease package inserts by the Food and Drug Administration (FDA). If the results are equivocal, how would this be documented? UNOS staff stated that there is no current guidance and would need to review this internally to determine how best to address this.

A member stated that equivocal results should be listed as an indeterminate result. Indeterminate is also depending on what test manufacturer is being used. Some tests will call it an indeterminate result while others will call it an equivocal result – it depends on the manufacturer. The Vice Chair voiced agreement and stated that whatever communications are put out to the community is consistent that there are times where results are neither positive or negative but there is a result delivered. In those particular scenarios, "indeterminate" is used as the result. UNOS staff stated that this messaging would be included in communication efforts.

UNOS staff added that the new extra vessel labels would be available during the summer. The challenging part of this project will be when the programming goes live – when DonorNet and TIEDI match up their disease test names and result options. Members will be required to update their TransNet mobile applications on the same day to stay in compliance. There were will be a number of communications to ensure that all members are aware of these changes and the requirements needed.

UNOS staff continued by stating that there is one more new infectious disease result that will be optional and not required to run a match run. This addition will go to DonorNet first as the added data entry will need to go through the Office of Management and Budget (OMB) approval before being added to TIEDI. The process can take some time, so the timeframe of when this addition will be approved is uncertain. Phases 2 (extra vessel final disposition report) and 3 for the project (scan of extra vessels and TransNet web application) will come after the implementation of the first phase, which is anticipated to be worked on furthing this fall or winter.

There were no further comments or questions.

6. Miscellaneous

The Vice Chair provided members with updates on the Committee's Post Recovery Test Results Sharing Project and the status of the liver allocation policy.

Post Recovery Test Results Sharing Project:

The Vice Chair stated that there were no updates but wanted to let members know that this project was still being worked on. Once updates become available, they will be shared with the Committee.

Liver Proposal Update:

The Vice Chair stated that as a result of a lawsuit, a temporary restraining order request has been filed on the liver allocation policy. The implementation of the liver allocation policy has been delayed until May 14, 2019.

UNOS staff updated members that the fall in-person Committee meeting will be held on October 24, 2019. A save the date will be sent to members with further details.

There were no further comments or questions. The meeting was adjourned.

Upcoming Meetings

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