

**OPTN Operations and Safety Committee
Meeting Minutes
June 27, 2019
Conference Call**

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

Introduction

The Operations and Safety Committee met via teleconference on 6/27/2019 to discuss the following agenda items:

1. Data Collection Proposal
2. ABO Project Update
3. HLA Initiative
4. TransNet Update/Mockup
5. Project: Committee Charge

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

1. Data Collection Proposal

UNOS staff provided members with an update on the Committee's Data Collection proposal.

Summary of discussion:

UNOS staff began by updating members on the Committee's Data Collection proposal. The proposal was presented to the Executive Committee which was approved to continue through the public comment cycle. The proposed data elements were reviewed by the Committee. UNOS research staff currently calculate distance of organ travel and it was agreed that this information could be used rather than proposing distance as a data element. To prevent redundancy in reporting, the data element of distance was removed. There were no comments or questions regarding the data elements.

UNOS staff continued by explaining that a sizing estimate and programming plan needed to be included in the public comment proposal. In order for this to be completed, the Committee was asked to propose a source document where the data would be collected. Members were asked to discuss and vote on the following forms that had been previously discussed or suggested through feedback from other OPTN Committees:

- Deceased Donor Registration (DDR) form
- Donor Organ Disposition form
- Transplant Candidate Registration form (TCR)
- Transplant Recipient Registration form (TRR)

A member stated that the TCR form would not be appropriate for the data being proposed as the TCR form is filled out when putting a candidate on the list. The Committee Chair agreed with this and asked if the TRR would be an option. The member replied that this data collection effort should be driven by the OPOs. There is a component for the transplant program to verify how the transportation happened. If this is done, then it would be appropriate to use the TRR or the 6 months follow up form.

Another member stated that from the transplant program perspective, the data on transportation is not readily available as they do not perform their own recoveries. Due to this, there is a concern as a transplant program how there would be visibility of some of the information being proposed. A member agreed with this and added that it would be unusual for the user who fills out these forms would have this information from the transplant side.

The Vice Chair agreed that the data collection should be driven by the OPO and the source document used to collect this data would be more appropriate with adding fields to either the DDR or Donor Disposition form.

The Committee Chair agreed with this and added that the transplant programs wouldn't have access to a lot of the information being requested. One of the data elements that would need input from the transplant programs would be organ check in to determine the timing based on organ check in and when the last label was scanned. Based on feedback received, the Committee acknowledges that transplant programs do not always perform the check in themselves and this would create a burden where the programs would have to develop a policy or procedure to collect this information so that it will get submitted.

A member asked if there would be additional burden on the OPOs in cases where the transplant programs do manage their own transportation arrangements. The Committee Chair stated that this was a valid point as it pertains to organs other than kidney. The Committee Chair asked if there was a way to suggest including a question to the Donor Organ Disposition form asking if the OPO coordinated the transport. If the answer is yes, then there will be questions for the OPO to complete. If the answer is no, then the questions would go to the recipient's TRR.

The Vice Chair stated that there is variability across the country and from a consistency standpoint, the data being proposed is more appropriate for the DDR form. The goal of the Committee, in developing the proposal, should be to put together what is thought to be for how and where the data should be collected and allow others to weigh in on if they feel differently or have other ideas.

The Committee Chair agreed with this and called for a vote. The Committee unanimously voted on proposing the DDR form to collect the data elements being proposed.

UNOS IT staff stated that this data does not necessarily have to be entered on a form. There are other means where the data could be collected. TransNet web, for instance, could have an interface created that would not need the same approvals or have the same challenges with the systems, and both transplant centers and OPOs would be able to access it. There would need to be further discussion on the filtering and the authenticated user to enter this data, but the interface could easily be available.

The Vice Chair stated that this was a great suggestion due to the fact that it would be easier to program and it is assumed that this pathway would not need to go through the OMB process, however, as the information being proposed is limited, it would be ideal from a consistency standpoint to have this information entered in a central location that everyone uses.

UNOS IT staff voiced agreement and added that the challenge with using the DDR form is the fact that it is a policy required form that must be submitted within 30 days of the procurement date. If the fields being added is not a policy required field on a policy required form presents some confusion in how compliance would intertwine with this.

A member stated that on the DDR form, there are currently fields on the form that are not required fields. The key is that the DDR is a policy required form but there are already existing fields that are not policy required fields. If it is a policy requirement to complete the data, then they would be required

fields to the DDR. In the same manner, the Donor Disposition form also has a policy requirement as far as completion is concerned, but there are already existing fields that are not policy required and can be skipped.

Next steps:

- UNOS staff will include the DDR form as the proposed data collection tool in the public comment document.
- A feedback question will be included to ask if the DDR is the appropriate data collection tool to use for this data collection.

2. ABO Project Update

The Vice Chair provided an update on the ABO project.

Summary of discussion:

The Vice Chair began by providing members with a recap of the ABO Workgroup's last meeting. The discussion was around the impact of massive transfusion on blood type. The takeaway from the discussion was that a massive transfusion is not the only case that can create a mixed field reaction. There are some cases where a few units of blood that are a compatible but not identical blood type that can also create a mixed field reaction that causes difficulty in identifying ABO. The workgroup plans to include discussion on not only massive transfusions, but any transfusions that may be of a compatible but non-identical blood type in the guidance document as education to members.

The next steps for the workgroup is to move from the discussion stage to the work point where the workgroup will begin to develop the guidance document and policy language that would be proposed.

3. HLA Initiative

The Committee Chair provided an update on the HLA initiative.

Summary of discussion:

The Committee Chair began by providing members with an overview of the HLA initiative. The Committee had a previous discussion with Histocompatibility (Histo) Committee Leadership. Histo Trac is one of the main tissue typing software vendors that is currently working on creating an interface in UNet. The Histo Committee Chair has been looking to communicating with UNOS IT to see if it is possible to do a trial or test case using Histo Trac as the example to work out any kinks about a possible direct communication interface between Histo Trac and UNet. As discussed in the past, this initiative will be a long process but there is some progress being made.

UNOS IT staff stated that there are a couple of pieces that would need to come into play first. The Histo Committee are working on an Unacceptable Antigen API project as well as a Board project. The Unacceptable Antigen API project will focus on the backend of the unacceptable antigens that will begin in August. The Board project from the Histocompatibility Committee is expected to being this fall where the Histo Committee will work on the HLA Typing errors aspect. Once this project is completed, the API project will then be worked on. It is not believed that these projects can be worked on in parallel due to the technical implications of working in the system. UNOS IT staff volunteered to check in with the staff who are working with the Histo Committee to see if there are any additional updates to share with members.

4. TransNet Update/Mockup

UNOS IT staff provided an update on TransNet and shared a mockup demonstration with members.

Summary of discussion:

UNOS IT staff focused the discussion and demonstration on the last aspect of the extra vessels project. This includes the scanning of the extra vessel barcode to view the donor infectious disease results in the TransNet website. In this project, UNOS IT staff redesigned the screens to make them more user friendly. Members were shown the redesign of the TransNet homepage. The homepage includes the same functionality as before with one extra option of extra vessels being added.

The Committee Chair suggested that the login should be in a bigger font so that it is obvious to users. A member asked that once the user logs in, would there be changes on that screen or are the changes just on the initial screen. UNOS IT staff stated that the main changes would be the homepage and extra vessels screens.

UNOS IT staff continued by reviewing the extra vessels screen. The new label and instructions were displayed. A warning message pops up if a donor is PHS increased risk. The warning message does not serve as consent or compliance purposes but is more of making the OR aware that the donor is PHS increased risk. Once the warning message is acknowledged, the screen will show all infectious disease results. The only difference is that the hemodiluted aspect was switched with the result aspect. From discussion with users, it was identified that the result details are more important and in real time what is being looked for. This list can be printed.

A member asked if there was any feedback from public comment last year that mentioned having an "Other" or free text option. UNOS IT staff stated that the current vessel label has an "Other" option to make the label compatible with newer tests before UNOS IT could program them. With the new changes, there will not be any other options for users to fill out or document as everything is hard coded. Everything that is listed is a test name that is consistently named across all systems and labels.

Another member stated that there was also a policy language statement, "all infectious disease results must be documented on an extra vessels labels" that created problems. The intent of the term "all" was in reference to all results from the serologies that are required, but it was being interpreted as all results ran are to be documented. UNOS IT staff agreed with this and stated that in the future the label would only include eight infectious diseases.

UNOS IT staff summarized that the plan would be to enhance all the other screens in TransNet. For instance, if a check in is performed, there would be an example of what the external label and shipping labels look like so that transplant programs would know which labels need to be scanned. This would not be tied into this project but it is the intent to make the functionality helpful to users.

5. Project: Committee Charge

UNOS staff provided members with an overview of a new project.

Summary of discussion:

UNOS staff began by providing background information on a new Committee project. The Committee is being tasked to review their current charge and make revisions as needed. Once revisions are made, UNOS Leadership will review the revised language and submitted to the Board for review and a vote during the December Board meeting. UNOS staff shared the Committee's current charge that is on the current OPTN website with members to review and begin discussing.

A member agreed that revisions should be made and added that when looking at the current Committee's charge, the Committee reviews data typically twice a year. Unless something is noted to the Committee about an adverse event, the Committee typically does not see all adverse events but

instead the aggregate overall data. The current mission statement does not encompass all that the Committee does.

Another member agreed and added that in looking at the Committee's current charge, it appears to be more of a charge as it pertains to safety rather than the operational aspect of the Committee's work.

The Committee Chair asked members to review the current Committee's charge and e-mail back revisions they suggest. The Committee Chair will review during that time and there will be further discussion on at the Committee's next teleconference on drafting language for the charge.

Next Steps:

- UNOS staff will send members the Committee's current charge to review and make edits. Members will send their feedback to Committee Leadership or UNOS staff for review.
- The Committee will discuss further during the next teleconference and begin drafting new language for the Committee Charge.

There were no further questions. The meeting was adjourned.

Upcoming Meetings

- July 25, 2019
- August 29, 2019