

OPTN Transplant Administrators Committee

Meeting Summary

October 27, 2020

Conference Call

Nancy Metzler, Chair

Susan Zylicz, MHA, BSN, RN, CCTC, Vice Chair

Introduction

The Committee met via Citrix GoToMeeting teleconference 10/27/2020 to discuss the following agenda items:

1. Welcome
2. DTAC Update
3. POC Update
4. IT Update
5. Data Lock Tools
6. Post Cross Clamp Workgroup Pilot
7. Organizational Excellence- Collaborative Improvement Projects
8. MPSC – Revisions to the Transplant Hospital and Transplant Program Membership Bylaws – Appendix D
9. Other Business

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

1. Welcome

The Chair thanked everyone for attending and welcomed a new member to the Committee.

2. Disease Transmission Advisory Committee (DTAC) Update

UNOS staff provided an update on the *Align OPTN Policy with U.S. Public Health Service (PHS) Guideline, 2020* proposal going to the Board of Directors (BOD) in December.

Summary of discussion:

UNOS staff shared that during public comment, the community had concerns around the requirement for storing living donor specimen for 10 years, the timing of the collection of deceased donor testing, and the requirement to assess and document hepatitis B (HBV) immunity.

DTAC reached out to Health Resources and Services Administration (HRSA) to see what the Committee would be able to change in response to the feedback received. The Final Rule requires alignment with PHS Guideline and HRSA provided a memo that outlined the level of adherence to the PHS Guideline required. However, it was determined that the OPTN does not have authority to require vaccination which was a component of the PHS Guideline.

In response to the concern about HBV documentation, candidates will only need to be asked if they are vaccinated and an answer of “yes, no, or unknown” will be added to their medical record. No supporting evidence is required. This information will be collected when completing an assessment prior to listing.

The PHS Guideline requirement for storing living donor specimens for 10 years is required to be added as OPTN policy as determined in the HRSA memo. There was a concern about informed consent raised by the Living Donor Committee. In response, language has been added to the policy that explicitly states that the living donor blood specimen will only be used for investigation of potential donor-derived disease. UNOS staff shared that DTAC took the public comment feedback received seriously but was unable to make a change to the length of the required storage time.

Members asked how many members will have the capacity to store these specimens and when implementation is expected to occur. UNOS staff shared that the planned implementation date is March 1. Members raised concerns about lab capacity as the space needed will be incremental and there will need to be a process developed for the destruction of samples over 10 years.

UNOS staff asked if a delayed implementation of this component would help members prepare. A member commented that labs are currently strained from COVID-19 and flu testing. A member asked if specimens need to be stored in the labs or at hospital. UNOS staff shared that is the responsibility of the transplant hospital to arrange storage whether that be onsite or at a lab. UNOS staff will explore if delaying the implementation to June is a possibility in order to allow for the programs to plan with labs and develop needed processes.

A member asked what the rationale is for requiring 10 years of storage. UNOS staff shared that it is to match the deceased storage requirement. A member asked if this requirement applies to living donors who are testing but then do not donate. UNOS staff will look into this to verify that it does not apply. A member asked if the donor or recipient hospital would be responsible for storing the donor specimen during kidney paired exchanges. UNOS staff shared that the responsibility is on the recovery hospital to make the arrangements.

UNOS staff shared that there is a cross walk to compare changes from 2013 to the most recent PHS Guideline to help programs review details when planning for implementation. A member raised a concern that DTAC did not fully assess the impact to labs. UNOS staff commented that the Histocompatibility Lab Committee reviewed the proposal and provided comment.

Next steps:

UNOS staff will follow up with TAC to share if a delayed implementation is possible for the 10-year requirement for living donor specimen.

3. POC Update

Summary of discussion:

The Vice Chair provided an overview of the Policy Oversight Committee's strategic priorities:

- Continuous distribution
- Multi-organ allocation
- Efficient donor/recipient matching to increase allocation

The Vice Chair reviewed the number of projects underway that fall under these priorities noting that continuous distribution related projects account for the majority of the overall effort of the three priorities. There are a number of other projects that do not fall under these priorities that are still important to pursue.

Efficient matching refers to mechanisms for reducing the time from offer to match to increase the utilization of organs. Projects that fall under this category are the provisional yes, biopsy standards, and

local recovery workgroups as well as the Data Advisory Committee (DAC) refusal codes/late turndown project.

TAC members are providing feedback to the continuous distribution and multi organ transplant projects. Several members are also participating on the various efficient matching workgroups and projects.

The Vice Chair asked if the members had any feedback on how TAC's work related to the strategic priorities and if they thought TAC should be collaborating on any other projects. UNOS staff will provide a list of projects for the members to review and determine which ones they may want to be involved with. A member commented they would like to have more data and insights to assess how projects such as the removal of donor service areas (DSAs) for kidney allocation will impact their programs. Members commented that they would like to be more involved early on in the proposal development process.

The Vice Chair suggested providing more presentations about proposals underway to TAC to review and respond to.

Next steps:

The members will be provided with a comprehensive list of projects underway. The members will choose which ones they want more information on or would like to be involved with.

4. IT Update

UNOS staff provided an update on several IT projects underway.

Summary of discussion:

The information provided on the following projects was also shared at the regional meetings.

UNetSM Image Sharing

The goal of UNetSM Image Sharing is to provide consistent, secure, and reliable access to high-quality medical imaging studies during the organ allocation process. Members are now able to view Digital Imaging and Communications in Medicine (DICOM) studies in UNetSM through a link in the donor record. This link takes you to an interactive DICOM image study viewer that has a tool set to allow you to zoom in and out, take measurements, or play the image study like a video. This project's pilot started with 7 organ procurement organizations (OPOs). Ten OPOs are being onboarded per quarter. If members do not see this functionality yet, the OPO is not yet onboarded.

Future features include the ability to send secure link of the image study to a non- UNetSM users, mobile access to imaging studies, and the ability to receive image studies directly from donor hospitals.

A member asked about the ability to download the DICOM files to be used for 3D modeling or other purposes. UNOS staff said this has not been discussed but they will bring this idea back to the team.

Offer Filters Phase 2 Pilot

The goal of the Offer Filters pilot is to increase the number of transplants by getting to "yes" faster by reducing unwanted offers, decreasing cold ischemic time, and increasing organ acceptance especially that of hard to place organs. Offer Filters will allow transplant hospitals to enter multifactorial criteria in order to screen offer more precisely.

All kidney programs have access to the Offer Filter explorer which is available in UNetSM data services portal. Members are able to examine how offer filters would affect offers received. Filter recommendations are provided using the last two years of acceptance data.

Phase 1 began in 2019. Phase 2 will consist of 45 kidney programs participating in the pilot from August through November.

Data Services Portal Enhancements

In response to the COVID-19 pandemic, UNOS IT has published the COVID-19 Weekly Recovery and Usage Maps or COVID-RUM report. The COVID RUM Report is an interactive Tableau dashboard aimed at providing the transplant community with the most current data available in response to the pandemic. This dashboard is a modified version of the Standard RUM report and is updated weekly with data from January 1, 2020 through the Saturday seven days prior to the update.

This fall, UNOS IT will be adding a Data Requests section to the Data Services portal. This will allow UNOS to deliver the results of a data requests through the data services portal rather than email. This will make the delivery of the data more secure, efficient, and convenient.

Additionally, a new data quality section will allow easy access to tools focused on ensuring the quality of OPTN data including data validation and data lock preview reports.

New DonorNet® Mobile

This pilot application that is a revamp of DonorNet® mobile and allows full access to donor records. Data will appear the same to OPOs and hospitals and allows for click to call for quick communication with OPOs.

For OPOs, this application supports the view of all donors added in the last 5 days, second ABO verification for donors, and allows OPO users to securely add new donor attachments, without saving images to the device used.

The transplant hospital features allow for the view of offers and the complete donor record, including attachments, as well as some candidate and match information to support informed decision-making as staff respond to offers.

UNetSM APIs

Another key focus area for UNOS IT has been on improving data information flow between systems to improve data quality and ease data burden. For the past several years UNOS IT has been building application programming interfaces (APIs) which are designed to allow other systems to connect and securely share information with UNetSM. This is to help reduce data burden by sending information to UNetSM from an electronic health records (EHR) system.

5. Data Lock Tools

UNOS Research staff gave an update and demonstration on the Data Submission “Data Lock” tool.

Summary of discussion:

Last December the BOD approved the Data Submission policy proposal from DAC. This proposal included the following:

- Removal of policy 18.4 (Timely Data Submission)
- Additional 30 or 60 days for eight TIEIDI forms (LDR, LDF, TCR, TRR, TRF, DHS, RHS, DDR)
- Implementation of a data lock for those same eight forms

The implementation of this policy has been delayed due to COVID-19. The emergency policies related to data submission amnesty due to COVID-19 will need to expire before this policy can be implemented. Tools were developed to assist members with these changes and were released on September 9th along

with educational offering in UNOS Connect. These resources omit TRF and LDR forms due to the amnesty policy but will be added in the near future.

The implementation of a data lock means that when the eight TIEDI forms reach their due date, they will no longer be editable. New data added and modifications will require unlocking and a reason will need to be provided for why the change occurred and who changed it.

The Data Lock Preview Report provides members with an easy way to review and correct data submitted on impacted forms prior to the forms being locked. The Data Lock Dashboard provides members with a way to compare the quality of their data to national results, monitor changes in their overall and element specific data quality over time, and review the frequency and reasons for “unlocking” forms at their institution.

UNOS Research staff showed an example of the Data Lock Preview Report spreadsheet. This report is updated weekly and includes all forms that have been generated in UNetSM but have not reached their due date.

UNOS Research staff gave a demonstration of the Data Lock Dashboard. This dashboard updates weekly and can be found in the data visualization tab in UNetSM.

The members were invited to reach out to Sarah Taranto in UNOS Research to share any ideas for enhancements.

6. Post Cross Clamp Workgroup Pilot

UNOS IT staff gave an update on the Post Cross Clamp Workgroup Pilot project.

Summary of discussion:

This project began in 2017 as an innovation event project at an Association of Organ Procurement Organizations (AOPO) conference and is intended to improve the efficiency in fulfilling the reporting requirements of policy 15.4.

Five OPOs and 20 transplant hospitals are participating in a three-month pilot. The pilot solution provides a notification system that OPOs can initiate when results are obtained post cross-clamp that may affect the recipient. This allows OPOs to notify transplant programs of test results including culture, pathology, and/or infectious disease as well as allows transplant programs to acknowledge that they have received notification and reviewed updated test results. An audit log allows OPOs to see when notifications are sent as well as when/if they have been acknowledged by the transplant program. This notification does not replace reporting in the patient safety portal but may in the future.

UNOS IT staff gave a demonstration on how this solution and process works.

User acceptance training is occurring between November 4-7. An email will be sent to participating members to notify them that the pilot is being released November 19th. Training materials will be provided.

Next steps:

Slides will be sent to the Committee to review. Members are invited to review and submit feedback to Emily Kneipp with UNOS IT.

7. Organizational Excellence- Collaborative Improvement Projects

UNOS staff from Collaborative Improvement (CI) gave a presentation on current CI projects.

Summary of discussion:

The CI team consists of four UNOS staff and collaborating partners across departments at UNOS. Each year, CI develops three to four projects. Information about these projects can be found on OPTN website under the “Improvement” tab.

CI projects are selected by ensuring there is a need by the community, there is a desire for improvement, an ability to provide positive impact, and there is an identified gap in practice. The project topics align with OPTN strategic goals. Maintaining a balanced portfolio of all populations and organ types is considered when initiating projects. CI projects are not research project, policy driven, or compliance related.

CI is currently working on four projects:

- Pediatric Liver Collaborative
- Potential Donor Referral Data Standards Demonstration
- Donation after Circulatory Death (DCD) Collaborative (currently on hold to not overburden members)
- Living Donor Collaborative- Liver

Next steps:

Members were invited to submit feedback and project ideas to ci@unos.org.

8. MPSC – Revisions to the Transplant Hospital and Transplant Program Membership Bylaws – Appendix D

The project manager for Membership and Professional Standards Committee (MPSC) gave an update to the upcoming revisions to the transplant program membership bylaws.

Summary of discussion:

The catalyst for this project was a contract task requiring the periodic reassessment of compliance with membership requirements. During this assessment, issues with multiple sections of membership requirements were identified by MPSC, staff, and members of community. This was the first comprehensive review of all membership requirements in over 10 years.

There are two documents going out for public comment. One includes proposed OPTN bylaw revisions to appendices A, B, C, and D and the other is a concept paper requesting community feedback on proposed transplant program key personnel training and experience requirement changes.

Proposed changes to Appendix D includes the removal of the requirement that a hospital be entirely within a single DSA as well as the removal of the requirement for documentation of the individual operating rooms. Maps of the building that contain the operating rooms will be required.

Changes to the requirements for documentation for transplant programs are minimal and the Appendix has been reorganized to have a better flow. Language has also been revised to make content clearer and more direct.

Other proposed revisions include requiring a financial coordinator and clinical transplant pharmacist on staff as well as a primary program administrator and primary data coordinator. The requirement for a transplant program director has been removed as has the requirement for primary surgeons and physicians to conduct assessment of all program surgeons and physicians. For programs without key personnel, there will be a 30-day grace period as well as an opportunity to request additional time before needing deactivation.

Members were reminded to provide feedback on the concept paper going out to public comment this January.

Next steps:

Members will receive the slides and a recap. Members will review and then provide feedback. The MPSC project manager offered to attend the next TAC meeting to answer any questions. Any questions in the meantime may be sent to Sharon.shepard@unos.org.

9. Other Business

Summary of discussion:

No other business was discussed.

Upcoming Meetings

November 18, 2020

Attendance

- **Committee Members**
 - Andrea Tietjen
 - Brian Roe
 - Denise Neal
 - Erica Seasor
 - Gene Ridolfi
 - Jason Huff
 - Joshua Gossett
 - Kelly Laschkewitsch
 - Kristina Wheeler
 - Melissa Porter
 - Michelle James
 - Nancy Metzler
 - Paul Myoung
 - Scott Wansley
 - Susan Zylicz
 - Travis Watson
- **HRSA Representatives**
 - Vanessa Arriola
- **UNOS Staff**
 - Angel Carroll
 - Beth Overacre
 - Emily Kneipp
 - Emily Ward
 - Lloyd Board
 - Peter Sokol
 - Sarah Konigsburg
 - Sarah Taranto
 - Shannon Edwards
 - Sharon Shepherd
 - Susan Tlusty