OPTN Organ Procurement Organization (OPO) Committee
Meeting Summary
April 15, 2021
Conference Call

Diane Brockmeier, RN, BSN, MHA, Committee Chair
Kurt Shutterly, RN, CPTC, Vice-Chair

Introduction

The Organ Procurement Organization (OPO) Committee (the Committee) met via Citrix GoToMeeting teleconference on 04/15/2021 to discuss the following agenda items:

1. Multi-Factor Authentication to UNet℠
2. Technology Tools Workgroup Update
3. Clarify Multi-Organ Allocation Proposal – Review of Revised Policy Language (Voting Item)
4. Modify Deceased Donor Registration Proposal – Review of Recommended Changes (Voting Item)

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

1. Multi-Factor Authentication to UNet℠

The Committee reviewed UNOS Information Technology's (IT) Multi-Factor Authentication for UNet℠ project and provided feedback.

Data summary:

Multi-Factor Authentication will reduce identity compromise risk by requiring users to prove identity via two different factors: knowledge factors, such as passwords, and possession factors, such as token codes produced by physical entities possessed by the authorized user.

Summary of discussion:

One member remarked that some users access UNet℠ as multiple transplant centers, and will need the ability to switch between these accesses without frequent re-authentication. Many users also do not have access to work phones, and don't want to link their own phones to UNet.℠

A member recommended working with multi-factor authentication vendors that already operate well within the healthcare industry and have already approved encryptions, so that hospital based UNet℠ users don't need a third or fourth authentication.

2. Technology Tools Workgroup Update

The Committee reviewed project recommendations and discussions from the Technology Tools Workgroup, and provided feedback on prioritization and requirements for these projects. The Committee also reviewed progress to date on the other Policy Oversight Committee assigned projects, including the Match Run Rules and Biopsy Standards Workgroups.

Data summary:

The Workgroup has discussed DonorNet® Mobile enhancements, improved in-app notifications, chat capabilities, post cross-clamp infectious disease results notification, and UNet℠ image sharing.

In particular, the Workgroup has focused on several recommendations and projects, including:

- Recommendation to create a single nodal or page to enter key recovery dates and times for OPO users in DonorNet® Mobile, including pronouncement and cross clamp date and time
- Priority for certain in-app notifications, including when a donor develops a positive infectious disease result, organ recovery and cross clamp, and key donation after circulatory death (DCD) dates and times.
- Recommendation that notifications be versatile and flexible in nature, allowing users to channel notification subscription and receipt to other users, such as surgeons to coordinators or coordinator to coordinator via shift change

Summary of discussion:

A member recommending updating DonorNet® Mobile to allow upload of multi-page documents.

One member suggested a mechanism to allow OPO users to notify kidney coordinators and surgeons when recovery has started, particularly for those with primary and first back-up offers.

A member asked if the timeframes associated donor after circulatory death (DCD) notifications would only include warm ischemic time. It was clarified that the timeframe would include key times up to and including when the donor has experienced cardiac arrest. The member supported this, and recommended including an option for notification when a donor doesn't arrest within the appropriate timeframe.

One member recommended notifications for OPO users when a high-ranking provisional yes becomes a decline, noting this would improve efficiency significantly. Other members agreed.

A member suggested prioritizing infectious disease notifications, particularly from a patient safety perspective. The member also recommended prioritizing recovery notifications, including DCD donor experiencing cardiac arrest, donor entering recovery, and cross clamp time. The Chair agreed, as did other workgroup members.

A member warned that chats and notifications could have the potential to overload OPO and transplant center coordinators on both sides.

3. Clarify Multi-Organ Allocation Proposal – Review of Revised Policy Language

The Committee review public comment feedback, the final rule, and the proposed transition plan, and discussed post-public comment changes to the policy language. The Committee voted to approve the updated policy language.

Summary of discussion:

Previously, the Committee discussed updating the policy language to include lung candidates under 12 years old and pediatric heart candidates in the medical criteria.

The Vice Chair spoke to including all active pediatric heart candidates and lung candidates under 12, noting that the initial proposal did not intend to exclude pediatric candidates, and that the relatively small population represented in this change will not significantly impact single kidney and liver candidates. The Committee reached consensus to update the proposed language to include pediatric heart and lung candidates under 12 years old.

The language of the proposed criteria "lung allocation score (LAS) of greater than 35" does not set a clear minimum boundary, which could cause confusion. For example, a candidate with an LAS of 35.00001 would be a required share, while a 35.0000 would not. Updates to the language, such as "lung

allocation score greater than or equal to 35" create a clear minimum boundary and include LAS 35.00000 candidates.

The Chair remarked that updating lung criteria language to "lung allocation score greater than or equal to 35" would improve clarity, so that there was no question if the minimum score was 35 or 36. Another member noted that the language should be clearly inclusive of LAS 35 and above. The Vice Chair agreed. The Committee reached consensus that the proposed language should be updated to "lung allocation score greater than or equal to 35."

The proposed policy language currently lacks operational clarity:

- "If the OPO is offering to potential transplant recipients (PTRs) appearing on either the heart or lung match runs" excludes the heart-lung match runs.

Updating the language away from "match run" resolves this issue, such as "if the OPO is offering the following organ [heart, lung]."

One member noted that the policy language should be clear about heart or lung, and it was confirmed that this proposal will not affect heart-lung allocation policy. Staff clarified that the intention this section of policy language was so that OPOs would follow the match run, and would be required to share the second organ when offering to candidates that meet the criteria on heart, lung, and heart-lung match runs. Other multi-organ shares are permissible. Several Committee members agreed.

A member noted that updating the language to "if the OPO is offering the following organ" adds clarity, as it requires to second organ to follow the first, and takes focus away from the match run. Another member agreed, remarking that this language makes it abundantly clear. The Committee reached consensus to update the policy language.

In order to align the remaining proposed language with operational clarity changes, this section must also be addressed:

- "If the OPO is offering to PTRs appearing on either the heart or lung match runs, and two PTRs appear that both meet the criteria in *Table 5-4*, it is permissible for the OPO to offer the second organ to the PTR on the heart match run or the PTR on the lung match run, at the OPO's discretion"

Updated proposed policy language could include "If the OPO is offering a heart or a lung and two PTRs meet the criteria in *Table 5-4*, it is permissible for the OPO to offer the second organ with the heart or lung."

A member noted that "either" clarifies intent, and another member recommended altering the language to "heart and/or lung." Staff noted this language operates with an inclusive "or."

One member asked if this language would establish priority between multi-organ combinations, and it was clarified that this is not addressed in the current proposal.

Another member noted that the use of the word "permissible" confuses the intent of this section of policy language. Instead of giving the OPO discretion to offer the second organ to either the heart or lung candidate, the updated language implies offering the second organ itself is not mandatory, but permissible. Other members agreed, noting that the updated language should be reorganized without the word "permissible." Members recommended re-incorporating the words "when" instead of "if" and "either," to provide additional clarity.

Staff presented a second option to update the proposed policy language:

- "When the OPO is offering a heart or a lung, and two PTRs meet the criteria in *Table 5-4*, the OPO has the discretion to offer the second organ to either PTR"

Several members supported this updated proposed language option. The Committee reached consensus to update the proposed policy language to "when the OPO is offering a heart or a lung, and two PTRs meet the criteria in *Table 5-4*, the OPO has the discretion to offer the second organ to either PTR."

After reviewing updated proposed policy language, the Committee made an organizational edit, reordering mandatory sharing language together and moving permissible language after that.

Vote: The Committee voted unanimously to approve and send the finalized, updated proposed policy language for the Clarify Multi-Organ Allocation Policy proposal to the Board of Directors for consideration.

4. Modify Deceased Donor Registration Proposal – Review of Recommended Changes

The Committee reviewed the Modify Deceased Donor Registration (DDR) Proposal and public comment feedback, and discussed post-public comment changes to the proposal. The Committee voted to approve the finalized proposal.

Summary of discussion:

The Committee reviewed several data elements that received no feedback during public comment and discussed moving these data elements forward as proposed.

- First name, Last name: "If the donor identity is unknown, enter the hospital-generated alias"

The proposed alteration to the First name, Last name data element is "If the donor identity is unknown, enter the hospital-generated alias." One member noted that some cases, OPOs generate an alias, as different donor hospitals may have too similar aliases. Another member commented that the use of hospital alias allows the donor information to match that of the hospital records, reducing confusion. The Committee agreed that hospital alias is the appropriate alias to require in cases where donor identity is unknown.

- Weight: data definition updated to be "weight of the donor at time of hospital admission"

The recommended update for the weight data element would define weight as weight "at time of hospital admission." One member noted that "time of admission" could be challenging, as many hospitals estimate on admission, rather than taking a bed weight. Another member suggested updating the proposed language to "first measured weight after admission." Other members agreed that this would provide the most accurate weight.

A member noted that the language in the weight data element included "if donor's weight at time of recovery is unavailable, select the reason," but that donor weight is necessary to execute match runs in DonorNet®. Other members agreed it would be very unlikely that the donor's weight would not be known. One member noted that keeping this field in the data element ensures that rare cases where an estimated weight was used, such as a crashing DCD, are captured as estimations.

- Terminal lab data: several small modifications to mitigate inconsistencies when additional lab tests are performed during recovery

A member commented that these changes clarify that lab values captured during organ recovery are not accurate terminal lab values, and are often discrepant from hospital labs. Others agreed.

- Inotropic medications at time of cross clamp: updated labels to be inclusive of DCD donor data

One member suggested that TransNet℠ and DonorNet® be updated with these changes in order allow easy cross over with the DDR tables.

Other data elements set to move forward as proposed received no questions or comments from the Committee, including those data elements proposed for removal from the DDR.

The Committee reviewed mixed feedback collected during public comment regarding several data elements, including DCD serial data, coronary angiogram, cancer free interval, citizenship, donor management, number of transfusions, clinical infection confirmed by culture, history of Chagas and Tuberculosis (TB), and recovery date.

- DCD Serial Data: If controlled DCD, measures between withdrawal of support and circulatory standstill/death. Provide serial data every 5 minutes between withdrawal of support and start of agonal phase, and every 1 minute between start of agonal phase and cardiac standstill. Should this information be collected on the DDR, and how often? Should "core cooling" be replaced with "perfusion" or "flush?"

The community provided little feedback on this, though some professional organizations felt DCD serial data was important to collect. One member noted that DCD serial data is critical upfront for donor evaluation, but may not be necessary in the DDR, as aggregate DCD serial data may not be useful for researchers. Warm ischemia time should be included in the DDR as an important retrospective item, but a full set of serial data may not be necessary. Another member agreed, adding that including this information is overly laborious. The Committee agreed.

One member expressed concern that if DCD serial data is not required elsewhere, and that removal from the DDR may cause OPOs to stop collecting and sharing it with transplant centers. Another member responded that this information will likely still need to be collected, as the moment the donor enters the agonal phase is still required reporting. Similarly, OPOs realize that most transplant programs want this data in order to evaluate organ offers, and will likely not stop sharing it. A member pointed out that this information is not directly collected in DonorNet®, making data entry burdensome in the DDR. Other members agreed, sharing that most OPOs upload DCD serial information as an attachment in DonorNet®, and that availability of this info should not change. The Chair also noted that information such as this is completed post-case any way, and is most critical reported in real-time in DonorNet®.

A member recommended removing DCD serial data form the DDR, and finding a way to ensure collecting and reporting that data to transplant centers is required by policy. Others agreed. The member continued that this data could qualify as donor management information under *Policy 2.11: Required Deceased Donor Information*, as well as required monitoring of vital signs under *Policy 2.13: Deceased Donor Management*.

There was Committee consensus to remove DCD serial data from the DDR. The Committee also agreed to replace "core cooling" with "flush," noting that perfusion could also reference organ pump mechanisms.

- Coronary Angiogram: The American Society for Transplantation (AST) recommended updating options to:
    - No
    - Yes, normal (no evidence of coronary artery disease)
    - Yes, abnormal but non-obstructive (all stenosis determined to be less than 70 percent)
    - Yes, abnormal and obstructive (presence of any stenosis determined to be greater than 70 percent)

One member pointed out that the proposed language, which only differentiated between normal and abnormal, was developed with input from the OPTN Heart Transplantation Committee.

A member commented that the AST recommendation provides clear definition on normal and abnormal. Other members agreed, noting collection of this data will not be burdensome.

The Committee agreed to put forth the data element with the AST's recommended changes.

- Cancer Free Interval: Enter the number of years the donor has been free of any sign of cancer. Should this be removed or retained?

This data element was initially recommended to be removed from the DDR, as it is often unreliable and dependent on historian knowledge of cancer treatment and timeframe.

One member expressed that the cancer free interval is important to initial clinical decision making, but less useful from a data standpoint. Another member pointed out that this data element doesn't cascade from the DonorNet® history of cancer field, and only appears in the DDR. Members agreed that the data element is relatively unreliable, and that the element provides little value from a data standpoint.

The Committee agreed to remove "cancer free interval" from the DDR.

- Citizenship: Indicate the donor's citizenship - United States (US) Citizen, Non-US Citizen/US Resident, Non-US Citizen/Non-US Resident, and Unknown. Should this still be collected?

During public comment, the American Society of Transplant Surgeons (ASTS) recommended retaining the question with the addition of a "prefer not to answer" option, as it is relevant for acceptance and post-transplant monitoring.

A member noted that the ASTS recommendation allows for valuable data collection to recognize when foreign nationals save American lives while leaving space for donor families who may not want to give that information safely. Another pointed out that this data element currently has an "unknown" option, which performs the same function, and that keeping the question as is removes implication that this information is asked of donor families. One member agreed that this data point is helpful to collect.

A member remarked that the citizenship data element has questionable accuracy. Another member agreed, but countered that information on non-United States citizens saving American lives is critical information. Others agreed.

One member shared that the OPTN Ad-hoc International Relations Committee currently uses this data. Members agreed that use and utility of this information indicates the value of the data.

The Committee agreed to keep the Citizenship element as is in the DDR.

- Donor Management: Any medications administered within 24 hours prior to cross-clamp - steroids, diuretics, T3, T4, antihypertensives, vasodilators, heparin, etc. Should this list of medications be updated, and should more granular data on dosages and duration be collected?

Public comment produced a mixed bag of feedback. The AST pointed out that most medications are standard in donor management, and the ASTS thought adding a requirement for dosages and timeframes might be clinically laborious.

A member described the donor management data element, noting that the response options don't provide much information on the kinds of medications, such as diuretic types, and if the use was continuous or not. The member continued that incorporating a flowsheet into DonorNet® of these medications that could cascade to the DDR would be optimal. Another member noted that the information is somewhat granular in DonorNet®, and can be completed from an electronic medical

record (EMR) with the start time, end time, and dose. It just needs to cascade into the DDR to retain granularity. A member responded that this data element in DDR is currently a summarization of donor management, and allowing granular data to cascade from Donornet® would improve accuracy and value of the data element. Others agreed.

A member described the "other specify" option as a catch-all for many other medications. Other members agreed the lack of clarity for "other, specify" was frustrating. Other members indicated preference for granularity, as eliminating the data element would remove any ability to evaluate outcomes.

One member noted that some of the information carries over from DonorNet® into the DDR, and another recommended updating the DDR to better reflect information put into DonorNet®. A member remarked that this data often cascades both ways, so allowing the data to carry over to DonorNet®, be validated, and then cleaned up would allow for clean, complete information on both ends.

A member disagreed with retaining this data element as is, noting that the current entry of this information lacks accuracy and reliability. The data may not be a true representation of impact on the patient. Another member agreed, adding that increased granularity would need to allow some information to cascade from DonorNet®. Staff noted that this is only this first iteration of review of the DDR, and data elements can be further clarified and updated later on. Members agreed that rushing certain updates could result in poor and futile data collection.

The Committee agreed to leave the Donor Management data element as is, and will return to it in future discussions on the DDR.

- Number of Transfusions: Proposed change – transfusions during terminal hospitalization? Yes/No. If yes, enter total volume. Should there be a specific timeframe for reporting transfusions during the terminal hospitalization?

One member asked if this data element was meant to evaluate hemodilution, and another confirmed and clarified that this question also targets subtyping. The Chair added that the OPTN Operations and Safety Committee supported the initial recommendation of provided total volume as opposed to a number. Another member indicated preference to support that recommendation, since the Operations and Safety Committee has had many discussions related to blood and subtyping, and had issues pulling valuable data. One member noted that this would involve adding a timeframe, specifically prior to blood typing samples or else over the hospitalization.

Staff clarified that transfusion information cascades from DonorNet®. A member expressed concern that subtyping and transfusion history may not be captured appropriately in DonorNet®. Another added that this information may not be regularly updated in DonorNet® anyway, and instead updated once at initial Donor addition and once in submitting the final DDR. One member commented that OPOs likely already track the number of units and total volume, and simplify that data for DonorNet® and DDR entry. Requiring entry of more granular information will not actually overly burden OPOs, since this information is already being collected.

One member suggested allowing the number of units and total volume to be open fields for entry, in order to give an absolute number.

A member expressed support to include total volume, noting that there could be some challenge with each unit of blood varying in volume. Volume is more impactful on hemodilution and tissue, while the timeframe is more critical for subtyping. More granularity is required to build a valuable data element. Another member agreed that a timeframe will be needed to define "terminal hospitalization." A

member recommended pre-typing sampling and post-sampling, in order to delineate for subtyping purposes.

One member remarked that hemodilution is less of a concern regarding timeframes, and that the timeframes should center around blood typing specimen draw. The member recommended prior to ABO specimen withdrawal and after ABO specimen withdrawal. Another commented that this made sense, and would not be onerous to OPOs. A member clarified that the first part would be prior to the first ABO specimen withdrawal, since that is the driver. If blood was given between specimen withdrawals, the donor can't be subtyped anyway. One member recommended the language "prior to ABO determination."

The Committee agreed to update the transfusion data element to collect number of transfusions and total volume prior to ABO determination and post-ABO determination.

- Clinical Infection Confirmed by Culture: Is there documented evidence of any clinical infection (positive cultures) during this hospitalization? If so, what was the source (blood, lung, urine, and/or other)? Is more granular information needed here?

The Chair remarked that the OPTN Disease Transmission Advisory Committee had mixed feedback regarding granularity, but that granularity may have little value without clinical history or symptoms captured in the DDR. A member added that more granularity in this data element would be extremely difficult. Members agreed that granularity for this data element would need to be carefully constructed around what researchers would need.

One member pointed out that a positive culture does not always mean an infection. The Chair agreed, sharing that the OPTN Disease Transmission Advisory Committee felt the same way.

The Committee agreed to leave the data element as is, and return to it in future work updating the DDR.

- History of Chagas and Tuberculosis: Should additional information on Chagas and Tuberculosis be collected, including specific risk factors, to evaluate patient safety and outcomes?

A member noted that not every OPO tests donors for Chagas, but that indication of potential Chagas in medical-social histories often leads to increased testing efforts. Another member agreed, and noted that this kind information is only in the medical social history, and that there were few additional risk factors that could be added to improve risk and history evaluation. The OPTN Disease Transmission Advisory Committee recommended collecting information on scans, testing, treatment history and duration. A member noted that this information could not likely be collected accurately or reliably. Another commented that this information, if available, is shared with transplant centers via DonorNet®, just not necessarily in the DDR.

The Chair remarked that there was little public comment feedback on this item, and that many felt this data element was sufficient.

The Committee agreed to leave the History of Chagas and Tuberculosis data elements as is.

- Recovery Date: should both recovery date and Cross Clamp date and time be collected?

Recovery data heavily dictates policy around extra vessels, and moving to collecting only cross-clamp date and time will require significant changes to these policies and TransNet℠.

A member remarked that the OPTN Operations and Safety Committee explored transitioning away from "recovery date" and towards cross-clamp date and time, and had full support from this Committee. Currently, extra vessels policy utilizes multiple definitions of recovery date, and updating this policy will require significant input from the OPTN Data Advisory Committee.

The Committee agreed to work towards removing Recovery Date in the future, and leave the current data element as is for now.

Vote: The Committee unanimously approved to send the updated recommendations to modify the DDR, as discussed, to the Board of Directors.

Next steps:

The Modify Deceased Donor Registration Workgroup recommended another project to address data elements like cause, mechanism, and circumstances of death. This project can also address additional data elements identified by the Committee as needing further discussion and development.

Upcoming Meetings

- May 19, 2021 – Teleconference
- June 16, 2021 – Teleconference

Attendance

- **Committee Members**
  - Diane Brockmeier
  - Kurt Shutterly
  - Bruce Nicely
  - Catherine Kling
  - David Marshman
  - Debra Cooper
  - Jeffrey Trageser
  - Jennifer Muriett
  - Jill Grandas
  - Jillian Wojtowicz
  - John Stallbaum
  - Lawrence Suplee
  - Malay Shah
  - Mary Zeker
  - Meg Rogers
  - Sue McClung
- **HRSA Representatives**
  - Adriana Martinez
  - Jim Bowman
  - Shannon Taitt
  - Vanessa Arriola
- **SRTR Representatives**
  - Ajay Israni
  - Donnie Musgrove
  - Katie Audette
  - Matthew Tabaka
- **UNOS Staff**
  - Robert Hunter
  - Kayla Temple
  - Alice Toll
  - Alex Tulchinsky
  - Amy Putnam
  - Darby Harris
  - Elizabeth Miller
  - Kaitlin Swanner
  - Lauren Motley
  - Leah Slife
  - Matt Prentice
  - Nicole Benjamin
  - Randall Fenderson
  - Rebecca Murdock
  - Sara Moriarty
  - Greg Edwards
- **Other Attendees**
  - PJ Geraghty