OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Data Advisory Committee
Meeting Minutes
March 25, 2019
Conference Call

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Introduction

The Data Advisory Committee (DAC) met via Citrix GoTo teleconference on 03/25/2019 to discuss the following agenda items:

1. Data Definition Process
2. Analysis: 2018 Center Data Submission
3. Data Submission Requirements

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

1. Data Definition Process

UNOS staff presented an overview of the UNOS Data Governance department, including current projects. For the Data Definition Process, this project requires that the DAC review and provide quarterly feedback on proposed changes to OPTN data definitions.

Data summary:

Table 1: *FY 2019 Q2 Data Definition Updates*

Publish Date	Data Element	System	Form	Change Type	Description	Reviewed By
4/15/2019	Ventricular tachycardia (VT) or ventricular fibrillation (VF)	Waitlist℠	Adult Heart Status 2 Justification Form	Clarification	Anti-tachycardia pacing (ATP) can qualify as electrical cardioversion, in a hospital candidate on anti-arrhythmic medication.	Research SME, CMO, Thoracic Committee Leadership
4/15/2019	Has the candidate experienced hemoglobinuria?	Waitlist℠	Thoracic Justification Form	Clarification	Select Unknown if Urine Analysis was not done since submission of last justification form	Research SME, CMO
4/15/2019	New diabetes onset between last follow-up to the current follow-up	TIEDI®	Intestine, Kidney, Liver, Thoracic TRF	Clarification	Added guidance to address onset reported on previous follow-up forms. Clarified this excludes gestational diabetes.	Research SME, CMO
4/15/2019	Total Cold Ischemia Time	TIEDI®	Kidney TRR	Clarification	Total Cold Ischemia Time is the number of hours between donor kidney cross-clamp to recipient kidney reperfusion, with reperfusion being defined as when the first arterial clamp is removed and blood flow restored with warm recipient blood (i.e. first clamp removed in situ).	Research SME, CMO
4/15/2019	Graft Status	TIEDI®	Kidney TRR, TRF	Clarification	Reason for dual or en bloc kidney graft failure.	Research SME, CMO
4/15/2019	Initial Flush Solution, Back Table Flush Solution, Final Flush/Storage Solution	TIEDI®	DDR	Clarification	Equivalent solution should be selected when the specific name of a solution is not listed as an available choice.	Research SME, CMO
4/15/2019	Furosemide Torsemide Bumetanide Chlorothiazide Metolazone Other diuretic	Waitlist℠	Thoracic Justification Form	Clarification	Enter the maximum limit if value is above the maximum allowed limit, and enter the minimum value if it is below the minimum allowed value	Research SME
4/15/2019	HBV DNA	TIEDI®	Intestine, Kidney, Kidney-Pancreas, Liver, Pancreas, Thoracic, Thoracic - 6 Months TRF	Clarification	PCR and NAT testing can be used to submit response for the HBV DNA test, similar to the HIV NAT and HCV NAT test.	Research SME, CMO
4/15/2019	Patient on insulin?	TIEDI®	Kidney-Pancreas, Pancreas TRF, TRR	Clarification	Insulin dosage per day and duration of use is the number of days since the transplant occurred.	Research SME, CMO

Summary of discussion:

The first Q2 data definition that the DAC reviewed was on ventricular tachycardia (VT) or ventricular fibrillation (VF) on the Thoracic Justification Form (Adult Heart Status 2). Below is a summary of the proposed changes:

Proposed Definition:

Ventricular tachycardia (VT) or ventricular fibrillation (VF)

Candidate is admitted to the transplant center that registered the candidate on waitlist and is not considered a candidate for other treatment alternatives, such as ablation, by an electrophysiologist, and is experiencing recurrent or sustained VT or VF with at least three episodes separated by at least one hour within a period of 14 days. The VT or VF must have occurred in the setting of normal serum magnesium and potassium levels and required electrical cardioversion despite receiving antiarrhythmic therapies. Note: Anti-tachycardia pacing (ATP) qualifies as electrical cardioversion, in a hospitalized candidate experiencing VT on anti-arrhythmic medication.

UNOS staff noted that this specific data definition received input from the Chief Medical Officer at UNOS and the OPTN Thoracic Committee Leadership.

The next Q2 data definition that the DAC reviewed was about the reporting on hemoglobinuria on the Thoracic Justification Form (e.g. Risk Stratification Data). The goal was to try to capture, that if the test was not done, they don't want a member to answer yes or no. Below is a summary of the proposed changes:

Proposed Definition:

Has the candidate experienced hemoglobinuria? If the candidate has experienced hemoglobinuria at any point, select Yes. If not, select No. If unknown, select, Unknown. This is a required field. Note: If initially listing a candidate, indicate whether the candidate has experienced hemoglobinuria at any time prior to listing. If submitting a justification form, indicate whether the candidate has experienced hemoglobinuria since submission of the last justification form. If urinalysis was not repeated since the submission of the last justification form, select unknown.

Moving on, UNOS staff presented the next proposed data definition on the reporting of new diabetes onset between last follow-up to the current follow-up on TEIDI and Transplant Recipient Follow-up forms (TRFs) for intestines, kidney, liver and thoracic. The team broke out the language to clarify expectations. Below is a summary of the proposed changes:

Proposed Definition:

New diabetes onset between last follow-up to the current follow-up: The intent of this field is to capture NEW post-transplant diabetes onset since last follow-up period. If the recipient developed post-transplant diabetes since the last follow-up, select Yes. If no new diabetes diagnosis since previous follow-up, select No. If unknown, select UNK.

NOTE:

- *A patient should not be considered as having developed diabetes based on gestational diabetes only.*
- *If onset of post-transplant diabetes has been documented on a previous follow-up and has not resolved select NO.*
- *If previous post-transplant diabetes was reported, later resolved, and has been re-diagnosed during the most recent follow-up period, select Yes.*

A DAC member asked whether the data definition could be modified to simply ask whether the patient has diabetes (yes or no answer required). The reasoning is that if such a question is asked every year, then the OPTN should be able to ascertain when a patient develops new onset diabetes (e.g. the patient would have a newly reported "yes" compared to the previous year). In this way, the definition is kept simple for transplant hospitals reporting data. UNOS staff responded that the DAC member has a valid suggestion, however their suggestion would require a programming change (e.g. labels). As such, the suggestion fits nicely with how the DAC assesses data definitions and provides feedback on how to improve data collection. In the interim, though the proposed definition does not solve the convoluted phrasing of the question, the DAC agreed to the new definition so long as the Committee revisits this issue.

The fourth data definition to undergo change is Total Cold Ischemia Time reported in TIEDI on Transplant Recipient Registration forms (TRRs). Below is a summary of the proposed changes:

Proposed Definition:

Total Cold Ischemia Time is the number of hours between donor kidney cross-clamp to recipient kidney reperfusion, with reperfusion being defined as when the first arterial clamp is removed and blood flow restored with warm recipient blood (i.e. first clamp removed in situ).

Total Cold Ischemia Time must be reported for each organ. If both kidneys are transplanted into a single recipient in an en-bloc procedure, the kidneys will have the same total cold ischemia time. Therefore, it is not necessary to report the same time twice. However, if both kidneys are transplanted sequentially, each kidney will have a different total cold ischemia time that must be reported separately etc……

A DAC member questioned why the transplant centers need to calculate the cold ischemia time (CIT) if the OPOs are already reporting clamp time. The member was concerned that the transplant centers may calculate an erroneous cold ischemia time. UNOS staff clarified that the OPTN does not currently collect anastomotic time. However, the DAC members' suggestion is on par with improving future data collection processes, similar to what occurred with reporting warm time on DDR forms. The Committee agreed that collecting raw data and then calculating each CIT is preferred over having transplant centers calculate the data themselves. Due to time constraints, the DAC members agreed to the proposed definition and to revisit how CIT is collected at a future date.

Next, UNOS staff presented the proposed update to kidney graft status reported on the TRR and TRF forms. Below is a summary of the proposed changes:

Proposed Definition*:*

TRR: Graft Status: If the kidney graft is functioning, select Functioning. If the graft is not functioning at the time of hospital discharge or time of report, select Failed. If failed, complete the remainder of this section. This field is required. Note: Select Functioning if the recipient was removed from the waiting list with a code 21, indicating the recipient died during the transplant procedure. Note: If death is indicated for the recipient, and the death was a result of some other factor unrelated to graft failure, select Functioning.

TRF: Graft Status: If the graft is functioning at the time of follow-up, select Functioning. If the graft is not functioning at the time of follow-up, select Failed. Note: If death is indicated for the recipient, and the death was a result of some other factor unrelated to graft failure, select Functioning.

Note: If dual or en bloc recipient and only one kidney fails without patient resuming maintenance dialysis, this should be considered a functioning graft until patient resumes maintenance dialysis.

UNOS staff then proceeded to explain the current and proposed definitions for initial flush solution, back table flush solution and final flush/storage solution located on DDR forms. Below is a summary of the changes:

Proposed Definition:

The intent of Initial, Back Table and Final Flush/Storage fields is to analyze the effects of a specific composition of preservation solution.

Initial Flush Solution: For each recovered organ, select the flush solution from the drop-down list, used during the recovery procedure. If a solution was used that is equivalent to the solutions in the drop-down list, then select the equivalent solution. If unknown, select Unknown. This field is required. If Other, specify is selected, enter the flush solution used in the Specify field. If Other, Specify is selected, this field is required.

Initial Flush Solution Volume (mL): If the organ is either a liver or a pancreas and the disposition is recovered for transplant but not transplanted or transplanted, then enter the amount of flush solution used. Initial flush should be the total of the in-situ fluid which equals aortic and portal.

Back Table Flush Solution: For each recovered organ, indicate the back table flush solution used to preserve each organ. If a solution was used that is equivalent to the solutions in the drop-down list, then select the equivalent solution. If a back flush solution was not used, select No Flush. If unknown, select Unknown. This field is required. If Other Specify is selected, enter the flush solution used in the Specify field. If Other Specify is selected, this field is required.

Back Table Flush Solution Volume (mL): If the organ is either a liver or a pancreas and the disposition is recovered for transplant but not transplanted or transplanted, then enter the amount of flush solution used.

Final Flush/Storage Solution: For each recovered organ, indicate the final flush and storage solution used during the recovery procedure. If a solution was used that is equivalent to the solutions in the drop-down list, then select the equivalent solution. If unknown, select Unknown. This field is required. If Other Specify is selected, enter the flush solution used in the Specify field. If Other, Specify is selected, this field is required.

The next definition was regarding how diuretics (Furosemide, Torsemide, Bumetanide, Chlorothiazide, Metolazone, Other diuretic) are reported on the Waitlist Status Justification forms for thoracic organs. Below is a summary of the proposed changes:

Proposed Definition:

Enter the dosage of Chlorothiazide in mg. The entry must fall between 1 and 200. If the value exceeds the maximum acceptable limit, enter the maximum acceptable limit. If the value falls below the minimum allowed value, enter the minimum allowed value. Select IV (intravenous) or PO (per os (by mouth)).

Continuing the discussion, another data definition that has proposed revision is regarding HBV DNA reported on the six-month TRF forms for intestines, kidney, kidney-pancreas, liver, pancreas, and thoracic. Below is a summary of the proposed changes:

Proposed Definition:

PCR or NAT testing can be used to submit response. Select the results from the drop-down list.

Positive
Negative
UNK/Cannot Disclose
Not Done

The last data definition to change was about reporting patients using insulin on TRR forms and TRF forms for kidney/pancreas and pancreas. Below is a summary of the proposed changes:

Proposed Definition:

Patient on insulin? Select Yes, No, or UNK to indicate whether the patient is currently on insulin as of the patient status date. This field is required.

If Yes, complete the following fields:

Date insulin resumed: Enter the date insulin resumed using the standard 8-digit numeric format of MM/DD/YYYY. Date must be after date of birth and before and/or equal to today's date. If unavailable, select the appropriate status from the ST field (N/A, Not Done, Missing, Unknown). This field is required.

Average total insulin dosage per day: Enter the average daily total insulin dosage units (units/kg/day) in the space provided. Average daily insulin dose should be a total including all insulin administered in any form per day (short term, long term, by pump, subcutaneous). The insulin dosage units must be between 1 and 1000. If the value is unavailable, select the appropriate status from the ST field (N/A, Not Done, Missing, Unknown). This field is required.

Insulin duration of use: Enter the insulin duration of use (days) for the current dosage in the space provided. If unavailable, select the appropriate status from the ST field (N/A, Not Done, Missing, Unknown). This field is required.

The Committee members had no further questions, comments or suggestions on this project. The Vice-Chair asked about next steps with the definitions.

Next steps:

UNOS staff outlined that the next steps for the Q2 data definitions will be publishing the definitions online, and then notifying the transplant community via UNet. In terms of the suggestions brought forward by DAC members, UNOS staff will record both suggestions (CIT, reporting diabetes) in a backlog, which will then be referenced for future recommendations, on a quarterly basis.

2. Analysis: 2018 Center Data Submission

UNOS staff presented an analysis of all transplant center forms with an expected date during 2018 (in accordance with OPTN Policy 18.1: *Data Submission*). The data analysis looked at each center, organ type, and calculated the percentage of forms validated by OPTN expected data. Furthermore, the analysis provided ranges and medians across all programs.

During a previous meeting, the Committee requested some analysis of submission rates by center, by organ, and by form type. The analysis looked across all programs to determine the median and range. For purposes of analysis, a median of 95% would indicate that half of the

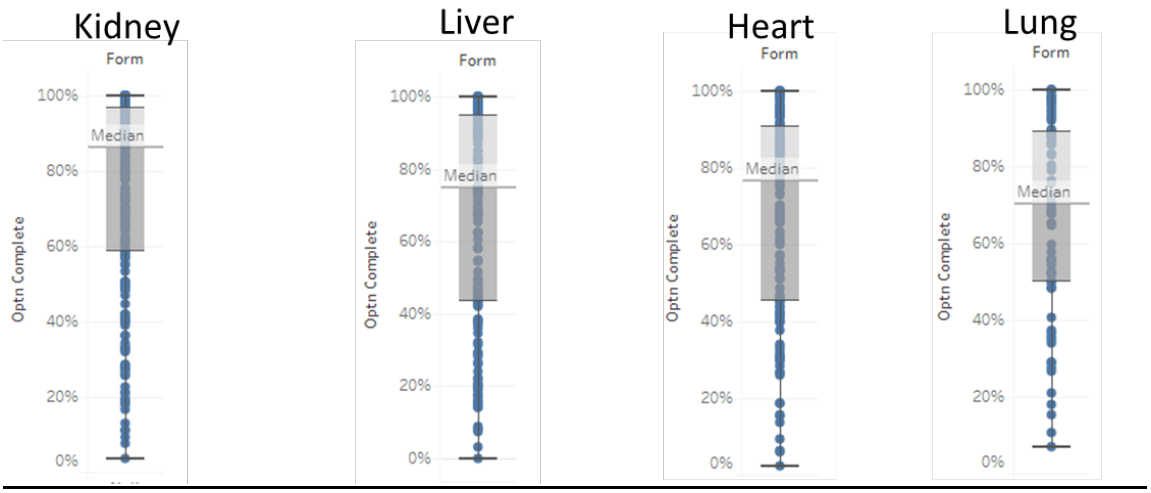
programs had at least 95% of their forms that were validated by the Policy 18.1: Data Submission Requirements expected date.

Data Summary

Overall, the median percentage, or about half of the centers are submitting about 75% to 85% of their forms within that Policy 18.1 expected date. However, there is an enormous amount of variability across transplant centers. For example, each of the blue dots shown represents a transplant center.

Table 1: Results of all forms combined

Organ Type	Results
Kidney	Median: 86% Range: 4%-100%
Liver	Median: 75% Range: 0%-100%
Heart	Median: 76% Range: 0%-100%
Lung	Median: 70% Range: 7%-100%



Overall, there was variation across organs and forms in timing of completion. The TRF was lowest for all organs, whereas the largest variation between forms was seen for kidney. There was also variation across centers in timing of completion, with both small and large programs having both high and low completion percentages, indicating that this is not a small versus large center problem. For instance, when comparing programs submitting more than 1,000 TRFs and 2,000 TRFs, the median increased for programs submitting more forms.

This analysis does not completely answer the question. However, the analysis is informative by showing that some centers are able to meet the requirements.

Summary of Discussion

In the following discussion, a Committee member asked about the consequences transplant centers face should they not submit data by the timeframes stipulated. UNOS staff responded that UNOS Member Quality validates against OPTN Policy 18: *Data Submission Requirements*, but collaborate with transplant centers to improve data collection within the specified timeframes. There are also reports available to transplant centers available in the Data Services

Portal which allows them to monitor their compliance with OPTN Policy 18: *Data Submission Requirements*. This educational tool can help facilitate discussion and identify any process issues.

A Committee member wondered whether there was a compliance differences between submitting the 6 month forms and the 1 year forms, then there is with submitting 2 year, 5 years forms etc. The reasoning for asking such a question was because from a transplant center perspective, a Committee member verbalized that UNOS has not contacted them regarding their compliance with OPTN data submission standards. Furthermore, one member vocalized that their transplant center works diligently to meet the CMS requirements for the simple reason that there is are significant consequences to not meeting CMS metrics. In this way, the Committee member theorized that the data presented may have been caused by transplant centers having an internal drive to meet CMS metrics due to the perceived potential consequences of not doing so (behavioral drive). UNOS staff responded that they can further analyze the longer versus short-term follow-up for each organ. Furthermore, a suggestion was made that follow-up forms be generated 1 month in advance of the recipient's transplant date, thereby allowing more time to complete the forms. However, another member responded that TRF forms are already generated a month in advance, though the living donor form does not generate until the transplant anniversary date. If true, that means there is less time to complete the forms.

Next Steps

UNOS staff will look further into analyzing the compliance rates between short versus long term forms (e.g. 6 month, 1 year, 2 year, 5 year, etc.)

3. Data Submission Requirements

UNOS staff discussed the next steps for reaching out to other OPTN Committees regarding the elimination of Policy 18.4, and to clarify the timeframes set forth in Policy 18.1.

Summary of Discussion

UNOS staff will notify other OPTN Committees about the DAC's plan to eliminate Policy 18.4 in order to clarify submission timeframes and establish a timeframe for data changes, after which changes are no longer possible to ensure data integrity.

In concurrence with the above, other OPTN Committees will be provided the opportunity to respond to the following questions:

- What impact, if any, would eliminating Policy 18.4 have on your members' ability to meet the other timeframes?
- What factors, if any, may be present challenges for your members when submitting data by the timeframes?
- What is a reasonable amount of time for Histo labs to ensure submitted data is accurate?
- What circumstances or factors require labs to revise previously submitted data?

UNOS staff will present the above discussion items to the OPTN Histocompatibility Committee meeting on 03/26/2019,

One DAC member expressed a strong desire to have a DAC member on each call with other OPTN Committees. Ideally, the DAC member would have expertise in the content area and relay feedback back to the Committee. UNOS staff agreed, and will reach out to schedule DAC members for calls with the OPTN Transplant Administrator Committee (TAC) and the OPTN Living Donor Committee (LDC).

Upcoming Meetings

- April 8, 2019
- April 22, 2019
- May 1, 2019

Attendance

- **Committee Members**
  - Nicole Berry
  - Marian O'Rourke
  - Rachel Patzer
  - Sandy Feng
  - Maryl Johnson
- **HRSA Representatives**
  - Janet Kuramoto-Crawford
  - Joyce Hager
- **SRTR Staff**
  - Bert Kasiske
  - Maryam Valapour
  - Alyssa Herreid
- **OPTN/UNOS Staff**
  - Kim Uccellini
  - Sarah Taranto
  - Eric Messick
  - Nicole Benjamin
  - Kimberli Combs
  - Mary Ellison
  - Catherine Monstello
  - Rebecca Murdock
  - Lauren Parker
  - Leah Slife