

**OPTN/UNOS Data Advisory Committee
Meeting Minutes
December 13, 2018
Conference Call**

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Introduction

The Data Advisory Committee (DAC) met via Citrix GoToTraining on 12/13/2018 to discuss the following agenda items:

1. Review Data Definitions
2. Modify Data Submission Policies Project

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

1. Review Data Definitions

UNOS staff outlined the process for reviewing the OPTN data definitions that are currently in policy. The five definitions the Committee agreed to review include the following: donor gender, liver total cold ischemia time, pancreas oral medications, thoracic prior cardiac surgery, and thoracic time of support.

Summary of discussion:

UNOS staff began discussion by outlining the reasons behind changing the data definitions. These changes encompass a need to respond to questions from UNOS members and workforce, improve quality of data and provide transparency in data changes. In order to address these issues, UNOS staff have analyzed data definition templates and established a new process for revising data definitions. The new data process identified five data definitions and put them through a rigorous multidisciplinary review. From this process, UNOS staff presented the first round of definitions for review including:

1. Donor Gender
2. Liver: Total Cold Ischemia Time
3. Pancreas: Oral Medications
4. Thoracic: Prior Cardiac Surgery
5. Thoracic: Time of Support

After the DAC reviews the updated data definitions, UNOS will release the updated definitions to the public in January 2019, which will include an intent for collection and revision history for each definition.

UNOS staff reiterated that working through the data definitions will allow the DAC to be better equipped to work with sponsoring Committees. Furthermore, the DAC will tackle the process on two fronts: responding to member questions and proactively working with other Committees moving forward with data collection. UNOS staff continued the discussion by outlining the four Committee goals for reviewing data definitions: consistent format of definition, revision history visible to members, routine quarterly updates, and adequate review and audit schedule.

Donor Gender

The following discussion revolved around the difference between the terms "gender" and "sex" during data collection. Currently, the OPTN uses the term gender when collecting data, even

though based on review, the OPTN has intended to capture sex (including the biologic and physiologic traits at birth). However Committee members questioned why the term itself has not changed to “sex” if that is the intent for capture. An example of these data terminology inconsistencies can be found in screening criteria on the waiting lists for lung and heart/lung candidates, the PELD calculation for growth failure, and within clinical/non-clinical registries. Furthermore, the only term collected during data analysis is “gender”. UNOS staff stated that changing the label “gender” to “sex” would require significant IT programming. This programming would need to be done across several OPTN programs including TEIDI, DonorNet, and Waitlist.

However, Committee members continued to express concern that there is little clarity when asking for “gender” and in reality wanting members to enter “sex”. Committee members were unclear whether the term “gender” should still be included on the forms. The DAC felt that there needs to be further clarification. However, Committee members noted that staff entering data may be aware of what to report for “gender” and may not need this clarification.

In conclusion, the Committee agreed that the DAC would need to evaluate the level of programming effort and the value associated with this particular proposed change.

Liver: Cold Ischemia Time

Committee members reviewed the proposed definition for liver cold ischemic time. One concern from the Committee members was how UNOS derived the proposed definition. UNOS staff explained the process, such as incorporating the expertise of the UNOS Chief Medical Officer and OPTN Committee leadership. DAC members opined that they would be hesitant to revise any particular definition if subject matter experts have not already weighed in on any potential changes.

Another concern that DAC members had was in regards to the phrase “pumping time” and its inclusion within the proposed definition. UNOS staff explained that there is currently no separate data collection for “pumping time” and that UNOS provides such information in guidance documents. Though the DAC members reiterated that they are not clinical experts, the Committee members stated that the “pumping time” of livers increases “total cold ischemic time”.

However, another Committee member opined that the DAC should not collect or define a variable base on how one might potentially analyze that variable in a registry. For example, regardless if the DAC extends the total cold ischemic time to include “pumping time”, this would be irrelevant to the definition. As such, total cold ischemic time should be from time of clamping to time of anastomosis. Furthermore, a Committee member suggested that a separate variable could collect data on how long a liver has been on a perfusion pump if the Committee believes that there is a benefit for using perfusion pumps. In this way, the DAC could prevent data quality issues such as having data entry users identify the amount of time pumping (e.g. users making judgment calls). Other Committee members agreed, adding that the DAC should evaluate which additional data elements need to be included in order to build robust registries.

SRTR commented that the recipient form might include the date and time of reperfusion, instead of including it within total cold ischemic time. Other Committee members agreed, stating that the perfusion pumping of livers is not always “cold” within the machine after the first clamp is removed. As such, the word “cold” is not appropriate for all organ reperfusions and should be evaluated by the DAC later on.

Furthermore, another Committee member suggested that the recipient transplant form should state “reperfusion time is the time the clamps were removed in the recipient and it was reperused in situ”. The Committee member stated that it is important to include the statement

“clamp was removed in the recipient” because this emphasizes that the clamp was not removed in the perfusion machine. With this clarification, the OPTN can conduct a data analysis without having to rely on recipient transplant centers’ entering the correct reperfusion times, especially in regards to differing geographic time zones. Also, the DAC member would like to be able to extract the reperfusion times from OPTN records, instead of requiring manual time calculations.

In conclusion, Committee members agreed that instead of saying “the number of hours between donor liver cross-clamp”, that the phrasing should either state “liver reperfusion in the recipient” or “clamps were removed in the recipient in situ” because this will increase clarity with the statement “cold ischemic time”. Committee members agreed to continue to investigate the proper phrasing, so that this phrasing becomes clearer.

Pancreas: Oral Medications

The Committee members reviewed the proposed changes. One Committee member discussed the purpose of identifying insulin, regardless of how insulin is administered. Currently, the field for insulin only includes the phrase “oral medication”. UNOS staff informed the Committee that there is a small programming change that is required if the DAC wants to change this particular label. There was concern from the DAC that they need subject matter expert opinion prior to changing this particular label. However, UNOS staff replied that the Pancreas Committee leadership were consulted and they were the ones that revised the definition to include “injectable” for both insulin and non-insulin medications.

HRSA staff offered to provide information on the Office of Management and Budget (OMB) process, especially if the DAC is proposing to change multiple labels. The Committee members were receptive to this offer.

Committee members asked if a “parking lot” could be created to distinguish between the various levels of effort required to change certain data definitions and labels. UNOS staff agreed to start this backlog or parking lot for the DAC.

Thoracic: Prior Cardiac Surgery

A Committee member opined that the rationale for this definition change was focused on identifying whether a candidate has had a median sternotomy, because this surgery increases future surgical risks. However, this member believed that a transplant care coordinator may not know how to exactly provide an answer, because there are many clinically invasive cardiac procedures. As such, the member opined that the statements should say “if the patient has had a median sternotomy”. Furthermore, a challenge with only saying “median sternotomy” is that there are some Ventricular Assistive Devices (VADs) that are being implanted via bilateral sternotomy, and in which the definition does not account for these procedures. As such, the DAC proposes changing the rationale for the definition.

However, another Committee member opined that since there is a lack of granular data at the registry level, then trying to refine this would be a mistake. SRTR staff agreed that surgeries done for congenital thoracotomies or clam shells could pose a risk and that the data are not granular enough. There was also concern that if candidates have a valve replacement for congenital heart conditions, would this be considered a risk if the procedure is done through the groin? In essence, there was concern that the data would not be capturing non-invasive procedures, even though they might not carry similar risk as traditional cardiac procedures.

One Committee member suggested that the DAC change the language to “has had previous cardiac surgery prior to listing”, and include a drop down menu for “median sternotomy” and “other”.

Another member had an idea that the OPTN provide CPT codes for specific cardiac surgeries, such as sternotomies. For example, the data care coordinators would be provided a list of CPT codes that they could choose from. However, another member opined that the data care coordinators may encounter issues if the CPT codes were used in this way.

Overall, the DAC is concerned about the intent of the definition potentially not reflecting the current conditions in the thoracic field and how to collect the data over time. The Committee agreed to consult with the Thoracic Leadership Committee in order to better understand what specific data they want to collect. UNOS staff will verify whether or not the Thoracic Committee Leadership had previously revised the definition.

Thoracic: Time of Support

UNOS staff informed the DAC members that this definition was passed by the Thoracic Committee Leadership. There were questions about this definition prior to implementation of the new adult heart allocation. UNOS staff wanted to include the definition in this new data definition process, because despite the new revised definition being approved and released, there was no specific notification sent. As such, this new definition will go out in January 2019. There was general consensus amongst the Committee members that this definition was clear.

One member expressed confusion as to why UNOS would direct people to enter the “earliest of the following: documented procedure start time, operation start time, surgery start time or incision time”. UNOS staff explained that the reason this phrase is included is that for the adult heart status qualifications is the phrase “earliest time” provides the greatest window for candidates to qualify under particular heart statuses. SRTR staff advised that this be made clearer on the form. For example, “incision time” might be too ambiguous on the form and can allow for too much interpretation. There was general consensus from Committee members that this would be appropriate.

Next steps:

UNOS staff asked for DAC members to provide feedback on the data collection process and the data definition review. One member suggested that they be provided information on how the data definitions are currently being collected and that there is documentation that experts are providing their opinion on the data definition changes. UNOS will finalize the communication plan, and on January 15, 2019, UNOS will publish changes for members.

2. Modify Data Submission Policies Project

UNOS staff reviewed the Modify Data Submission Policies Project and the proposed tasks lists for the project.

Summary of discussion:

UNOS staff and DAC leadership have been meeting internally about the project timeline and deliverables. There was consensus during these internal meetings to move forward with creating policy changes instead of the previously proposed concept paper idea. In this way, there would be aggressive outreach coupled with the proposed policy changes. Internally, UNOS staff had discussed creating a data submission timeline workgroup and a data lock workgroup. The proposed policy changes would be released for fall 2019 public comment.

UNOS staff created a list of proposed project tasks to be completed by June 2019 (outlined below):

- Establish principles for data lock: accuracy and right to correct data vs. transparency/integrity of record. Consider need to refine by data type.
- Rationale for data lock, including background/history evidence (SRTR report)

- Review policy and identify timelines to eliminate, rationale for timelines
- Review data submission compliance rates to determine if any timeline beyond 90 days is necessary
- Identify common practices for locking data bases (e.g. what do FDA clinical trials require)
- Assess the value in modifying the unknown/missing data options in UNet
- Craft policy language
- Identify stakeholder groups to provide additional insight or initial vetting of policy language. Could be TAC, TCC, TQI leadership, TMF, etc.
- Revise policy language after stakeholder input, as needed
- Prepare proposal for public comment

UNOS staff informed the Committee that since this is a fairly aggressive timeline, then there would need to be monthly Committee meetings, along with workgroup meetings.

Next steps:

UNOS staff and the Committee will create a detailed timeline of tasks. Furthermore, UNOS staff will schedule recurring DAC and workgroup meetings.