

OPTN Data Advisory Committee

Meeting Summary

November 7, 2022

Conference Call

Sumit Mohan, MD, MPH, Chair
Jesse Schold, PhD, M.Stat, M.Ed, Vice Chair

Introduction

The Data Advisory Committee (DAC) met via Citrix GoToMeeting teleconference on 11/07/2022 to discuss the following agenda items:

1. Discussion of draft *Data Quality Report* (annual data deliverable to OPTN Board of Directors)
2. Discussion of draft *Data Review Report* (annual data deliverable to OPTN Board of Directors)
3. Consent materials for Committee endorsement – Clarifying data definitions: HBV Vaccination Status

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

1. Discussion of draft *Data Quality Report* (annual data deliverable to OPTN Board of Directors)

Enterprise Data Management (EDM) and Research staff presented the *Data Quality Report* to the Committee. The purpose of this report is to provide a foundational assessment of current OPTN data quality, and in concert with the OPTN data review report, will provide the OPTN DAC with information necessary to formulate recommendations for improving the quality of official OPTN data. This report is an annual deliverable that the DAC Chair presents to the OPTN Board of Directors (Board) during each December Board meeting.

Data summary:

This report includes timely data submission, potential discrepancies, early look at Policy 18 amendment (“data lock) post-implementation, and analysis of reporting of implausible donor data elements on match runs.

Summary of discussion:

Availability: Early Look at Data Lock Post-Implementation

A member inquired about the data lock findings and if more granular information were available with regard to the reason for delayed reporting due to staff resource issues. EDM staff responded that while they do not have more granular information about this issue, by collecting this information they will better understand the issues transplant programs face in trying to meet the submission deadlines. A member suggested including the reason for unlocking by each form, as opposed to just the reason totals. This information can be found in the full data report.

A member inquired which reason that a center would use if they unlocked the form due to internal auditing. EDM staff clarified that additional help documentation was circulated to transplant centers detailing the reason to use each answer choice. The Chair suggested an internal process of reviewing the number of unlocking events due to an internal audit at each transplant center to determine if there are specific centers that are experiencing ongoing data issues. A member added that it would be helpful to

know which electronic health record (EHR) system the center used and whether the forms were built into the system or the program was manually entering them. The member added that if it is an automated process, there could be an issue with the mapping in the system. A member agreed that having a correctly mapped electronic record could reduce instances of human error. A member asked if the people unlocking the forms had a clinical or non-clinical background. While a staff member name is required when unlocking, the policy does not require their job title be included and does not indicate if they have a clinical or non-clinical background.

Staff noted that this is an early, 3-month report of the findings from the data lock implementation and the findings and trends will likely evolve as more information is collected. As the DAC continues to review the data collected from this policy, the Committee can consider if there are any further modifications needed.

A member inquired if there was a relative baseline for unlocking reports that the Committee could compare to the new findings. Baseline information is not included in this early report, but staff will review what information is available and how it can be incorporated into future monitoring reports. A representative from SRTR added their data review period occurs in October, which could be the reason there was an uptick in form unlocking events in October. A member recommended developing a hybrid model wherein transplant centers cause review their data prior to seeing how it will affect the coefficient in the SRTR Program Specific Report (PSR), which could aid them in augmenting the risk adjustment they are receiving. The group reviewed the quantity of unlocking events for the Transplant Recipient Follow Up (TRF) form and noted that unless there were graft failure or death the information in this form is not utilized for the PSR, so the high quantity is likely unrelated to the SRTR's data review period.

Accuracy: Reporting of Biologically Implausible Donor Values on Match

A member suggested developing a system to intervene when biologically implausible values are entered into OPTN forms. For numbers that seem potentially implausible, the Chair recommended a warning that popped up encouraging the individual to review the data to make sure it is correct. This would provide more of a recommendation to review the data entered, as opposed to a complete inability to enter data past a certain point. In reviewing the donor reported peak serum creatinine on match by organ, the Chair noted that the margin for error in this information is small as incorrect information could lead to non-utilized organs.

2. Discussion of draft *Data Review Report* (annual data deliverable to OPTN Board of Directors)

EDM staff presented the *Data Review Report* to the Committee. The purpose of this report is to summarize the DAC's efforts to improve data quality since the last report submission (December 2021), inclusive of planned and implemented changes to data collection sent to the OPTN Board for consideration during the December 2021 and June 2022 meetings. This report is an annual deliverable that the Chairs presents to the OPTN Board.

Data summary:

This report includes a review of OPTN data policies, recommendations to improve data quality (which include improving data definitions and the data review processes), integrating industry data standards, and data quality review.

Next steps:

Members are asked to send any questions or feedback they have to EDM staff by end of day Tuesday, November, 8, for the feedback to be incorporated in time with internal deadlines.

3. Consent materials for Committee endorsement – Clarifying data definitions: HBV Vaccination Status

EDM staff presented the updated HBV Vaccination Status definition for the Committee to vote on as a consent agenda item. This definition will be updated on the Transplant Recipient Registration (TRR) form.

Data summary:

Completion of the HBV Vaccine Series: Completed Hepatitis B vaccine series is recommended by the CDC through the [PHS Guideline](#) for all transplant candidates.

If the patient received a full Hepatitis B vaccination series prior to transplant, select **Yes**. Full series is defined by type of vaccine received and evidence of serologic response.

If not, select **No**. If unknown, select **UNK**. If **No** is selected, select the reason from the list.

Immunity- Seropositive based on lab assay

Medical precaution- Not vaccinated due to medical constraints

Time constraints- Has not received series or full series due to urgency of transplant

Patient objection

Product out of stock

Other, specify- May select if series is still in progress of completion. May also select if full series was completed, but there is no evidence of a serologic response.

If the reason is not listed, select **Other, specify** and enter the reason in the space provided. The intent of this data collection is to identify gaps in immunization to improve future safety by increasing donor pool and decreasing risk of unexpected HepB transmission. HepB is one of the most common transmissions and is one of the most preventable.

Summary of discussion:

A member recommended reviewing the answers submitted to the 'other, specify' option and determining if there were more specific answers that could be added as options. The member noted the instances where patients have been vaccinated but have not developed an adequate immunologic response. Staff noted that this definition has been reviewed by the Ad Hoc Disease Transmission Committee (DTAC) and the Transplant Coordinators Committee (TCC) and both endorsed the definition as is. The DTAC did discuss parsing out the answers to 'other, specify,' however, that would require additional review and discussion. As such, this definition is being modified in the short term to respond to the request from the community. The Committee voted unanimously to approve the definition.

Upcoming Meetings

- December 12, 2022
- January 9, 2023

Attendance

- **Committee Members**
 - Bilal Mahmood
 - Christine Maxmeister
 - Farhan Zafar
 - Jamie Bucio
 - Jesse Schold
 - Krishnaraj Mahendraraj
 - Megan Muldoon
 - Michael Marvin
 - Paul MacLennan
 - Rachel Patzer
 - Rebecca Barnoff
 - Sumit Mohan
- **HRSA Representatives**
 - Adriana Martinez
- **SRTR Staff**
 - Ajay Israni
 - Bertram Kasiske
 - Jon Snyder
 - Maryam Valapour
- **UNOS Staff**
 - Brooke Chenault
 - Eric Messick
 - Janis Rosenberg
 - Joel Newman
 - Kim Uccellini
 - Krissy Laurie
 - Laura Schmitt
 - Leonyce Moses
 - Matt Belton
 - Nadine Hoffman
 - Samantha Noreen
 - Serena Straub
 - Sharon Shepherd
 - Suhan Wang
 - Taylor Livelli
- **Other Attendees**
 - Kate Giles
 - Martha Cramer