

OPTN Data Advisory Committee

Meeting Summary

September 11, 2023

Conference Call

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

Introduction

The Data Advisory Committee met via Webex teleconference on 09/11/2023 to discuss the following agenda items:

1. Review and discussion of organ non-use coding data request
2. Data definition clarification consent agenda: Kidney Biopsy

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

1. Review and discussion of organ non-use coding data request

Based on Committee members' discussions during DAC's February 2023 meeting, a data request was submitted for further information about organ non-use codes in the OPTN Data System. The purpose of the request was analyze data to support a potential future OPTN project updating options for coding non-use reasons. The results of the analysis were presented as part of the 09/11/2023 meeting and discussed by the Committee members.

Summary of discussion:

OPTN contractor staff presented the findings from an analysis of the reason codes that OPOs report in the OPTN Data System to describe why an organ was procured for transplant, but not transplanted, otherwise referred to as "non-use." The analysis was performed to help the Committee determine whether opportunities exist to make the current codes more informative and more mutually exclusive. It was mentioned that the analysis was similar in scope to that performed for the Committee as part of the Refusal Code project, which was approved by the OPTN Board of Directors in June 2021. The initial monitoring reports of the Refusal Code project are available, with the two-year report expected sometime in 2024.

The analysis being shared today provides information about the non-use reasons being used. The results are intended to assist the Committee in considering: whether, from a user perspective, the current codes make sense given the context of the data being provided, and whether it would be a good use of the Committee's time to review and potentially revise the list of codes to make them more actionable for future data analyses of large-scale drivers of organ non-use.

The analysis and results are organized into four parts. First, to tabulate or plot frequencies of the non-use codes by organ and DCD status, where frequency permits. Second, to plot the non-use codes versus the refusal codes entered on the match run, by organ. Third, to analyze the content of the free text "other, specify" responses to determine if there are better data entry options to consider. Fourth, to analyze the time from cross-clamp to the final match run start time, stratified by non-use code and by organ. Descriptions of all of the limitations associated with the data and the analyses were provided.

In addition, the analysis also contains information about the “disposition codes” used. The disposition codes describe different scenarios, such as whether the organ was procured and transplanted, or whether it was procured and ended up being not used or donated for research, among others. Each organ that is procured has a final disposition documenting its final use. Organs that are procured, but not transplanted also have a non-use reason code assigned to them. That's the subject of the bulk of this request.

It was stated that it does not appear from the analysis that non-use itself has a single root cause. In part, this may be explained because the procurement pathways differ significantly by organ type. Also, cross-clamp occurs only once, but all donor organs must be procured at cross-clamp, resulting in different conditions for each organ. Thoracic organs are generally procured by teams from the potential recipient's transplant center who travel to and from the donor hospital by chartered flight. This means that thoracic organs are usually being transported shortly after procurement. Thoracic organs are also more sensitive to longer cold time than other organs. By contrast, kidneys are often procured by local recovery teams and transported by commercial flights, and kidneys are able to experience longer cold times than thoracic organs and remain viable for transplant. The differences in the timing of procurement and transport have an impact on how well a donor organ performs after being transplanted. Many different factors feed into how well the organs will do in the future. Additionally, information about the donor, the donor's organs, and the potential recipients is continually being updated to reflect more current information and changes in clinical conditions. The new information can lead to changes in previously held views; for example, a program that was prepared to accept a donor organ when some information was known about the organ, may determine the organ is no longer appropriate when more up-to-date information is available, and vice-versa.

The Committee was provided with several scenarios describing how organ non-use could occur. The scenarios include:

- A transplant program formally accepts an organ offer before cross-clamp, but determines the organ is no longer acceptable for their patient after cross-clamp. Due to timing, such as ischemic time, etc., the organ cannot be re-allocated. These are considered late declines.
- Before any transplant program formally accepts an offer, the organ is procured with the belief that it will be transplanted because its viability is similar to other organs that have been successfully transplanted in the past. However, after procurement, no program subsequently accepts the offer and the organ goes unused. These are considered to be organs procured with no formal acceptance.
- A mixture of the previous two, where the organ is procured without formal acceptance, but a transplant program indicates a willingness to accept the organ, only to decide later the organ is not acceptable for their patient, resulting in a late decline that cannot be re-allocated.

A high-level summary of the reasons non-use can occur was presented to the Committee. Members were reminded that non-use reasons vary considerably by organ type, as well as by DCD status. The use of the non-use code “No recipient located – list exhausted,” has increased over time. The non-use reasons do not necessarily align well with the majority of organ refusal reason codes entered for same donor-organ pairs. The time between cross-clamp and the final offer start varies considerably for some non-use reasons, even for the same organ type. How OPOs use the list of non-use codes varies, as noted by the fact that the analysis frequently found themes in the use of non-use free text that duplicated options already available among the existing non-use codes.

A 'disposition code' is entered in the OPTN Data System for every organ, organ segment, or laterality for which data are captured, and the disposition code is entered before the non-use code is entered. The Committee was presented with information about disposition codes that identified a donor organ as recovered for transplant, but which was not ultimately used. The results of an analysis of "organs recovered for transplant, but not transplanted" were provided for each organ type covering the timeframe 2013 through 2022. The reason "recovered for transplant, but non-use occurred locally" was the most frequently cited for all organs, except intestines. Other reasons included "shared and not-used," and "submitted for research."

The Committee next reviewed the results associated with the distribution of time between cross-clamp and the start of the last offer. The information provided reflects that the majority of donor kidneys are still being offered on the match run when cross-clamp occurs. The results also indicate that for donor lungs and hearts, cross-clamp occurs after the last offer has been made. Looking across all the organ types, the majority of match runs have stopped before cross-clamp occurs.

The Committee was then provided with a breakdown of the non-use codes associated with donor kidneys during 2013 through 2022. The non-use codes were further classified by DBD or DCD. The results indicate that for donor kidneys, the three most cited non-use reasons were the same for DBD and DCD, and they were:

- No recipient located – list exhausted
- Biopsy findings
- Other, specify

For donor kidneys dispositioned as "procured for transplant, but not transplanted," the non-use code "no recipient located – list exhausted" was used 53% of the time for DCD donors, and 43% of the time for DBD donors. The non-use code "biopsy findings" was reported approximately 27% of the time for DBD donors, and 16% of the time for DCD donors. 'Other, specify' was selected roughly 12% of the time for both DBD and DCD donors. Additionally, information was provided showing that for kidneys over the 10-year period reviewed, the use of 'no recipient located – list exhausted' increased over time.

A plot of the frequency of organ refusal reason codes by the cited non-use reason was next shared with the Committee. The information shared reflected cases where both kidneys were recovered, excluding dual or en bloc, but two different non-use reasons were recorded for the organs. When the data request was initially submitted, there was an expectation that there would be some level of consistency between the non-use codes entered by the OPOs and the refusal reason codes entered by the transplant programs. However, there turned out to be more diversity than was maybe originally expected. For example, the non-use code 'biopsy findings' was frequently used regarding donor kidneys, but there was greater diversity among the refusal reason codes entered by the transplant programs. The refusal reason codes included the use of 'biopsy results unacceptable,' but cited more frequently or as least as frequently were 'actual or projected ischemic time too long,' and 'organ anatomical damage or defect.'

Analysis results of the distribution of time between cross-clamp and the last offer for kidneys during 2013 through 2022 were also presented. As previously stated, for the majority of kidneys the final match run starts following cross-clamp. This is not the case for lungs and hearts, and perhaps livers.

The Committee was also presented information about the percent of kidneys identified with non-use free text themes. In developing the analysis, the text themes were classified as 'simple,' which involved being able to associate the theme to a small number of ideas or words, and medium and complex,

where more information was needed to develop a single theme or idea. Based on some of the results of the free text submissions, the Committee may want to consider improving the drop-down selections of the non-use codes to help reduce the use of “other, specify” as an explanation for why an organ was procured for transplant, but not transplanted. Additionally, there might be some themes identified in the analysis that are not included among the discrete options within the drop-down selections, that could be added to assist OPOs.

Following the presentation of the kidney-specific analysis, the results of the same analyses for liver, heart, and lung were presented. All of the results are available in the report, which was provided to Committee members ahead of the meeting. The report can also be requested by contacting OPTN contractor staff. It was also mentioned to the Committee members that they should feel free to bring any additional questions or comments about the report to the in-person meeting scheduled for September 28, 2023.

The Chair stated that he hopes the members had a chance to review the report ahead of today’s meeting and that they find the presentation useful. There is a lot of detail in the report. The Chair asked if members find the information useful and/or would they like to see it presented differently? It was mentioned that the members can always contact OPTN contractor staff with more questions.

Next steps:

Committee members were encouraged to continue reviewing the report, and to contact OPTN contractor staff with additional questions or comments.

2. Data definition clarification consent agenda: Kidney Biopsy

As part of the upcoming implementation of the Kidney Committee’s, standardizing kidney biopsy reporting and data collection proposal, there was a request to update the “kidney biopsy” data collection field. The data collection can be found in the OPTN Data System. The proposed update was reviewed and endorsed by leadership of the OPTN OPO Committee. The changes were also reviewed by two DAC members. Implementation is scheduled for 09/14/2023.

The change addresses using the results for the biopsy that was used in allocating the organ if multiple biopsies were performed. In the case of multiple biopsies being available, the change also provides the OPO with discretion on which results to submit as part of the allocation process.

A question was raised about whether the proposed policy actually provides discretion to the OPOs. It was suggested the policy proposal include some language that requires the OPOs to upload all biopsy results to the OPTN Data System, in case the results were needed in the future for donor organ evaluation.

It was clarified that the proposed policy to be implemented on 09/14/2023, did not impact biopsy reporting. Instead, the proposal identified the specific data fields that are going to be collected when biopsy results are collected. It was pointed out that in the future, the part of the OPTN Data System where this information will be organized will have capacity for storing one set of results. An important part of the proposal was to determine how is this information impacting allocation. The update to the data element is intended to ensure that OPOs input the biopsy results that are impacting allocation and that are the most clinically appropriate. It was also pointed out that there is policy language (*Policy 2.11*) that establishes a pathway for OPOs to provide all biopsy results. It was also mentioned that the intent

of the policy being implemented was to encourage increased uniformity, increased standardization, and what biopsy results are reported when biopsies are recorded. The OPTN Kidney Committee wants to ensure that when the standardization effort is implemented, that there is a definition that is workable and understandable, and that there are instructions that are workable and understandable.

Summary of discussion:

The Committee was asked to endorse the revisions proposed for Kidney Biopsy, following the Committee's discussion during the meeting.

Decision #1: The Committee agreed with the proposed changes.

Upcoming Meetings

- September 28, 2023 – In-person meeting
- October 16, 2023
- November 13, 2023
- December 11, 2023

Attendance

- **Committee Members**
 - Sumit Mohan, Chair
 - Rebecca Baranoff
 - Jamie Bucio
 - Katie Giles
 - Dustin Goad
 - Michael Ison
 - Paul MacLennan
 - Michael Marvin
 - Christine Maxmeister
 - Meghan Muldoon
 - Hellen Oduor
 - Jennifer Peattie
 - Julie Prigoff
 - Alicia Skeen
 - Allen Wagner
- **HRSA Representatives**
 - Adriana Martinez
- **SRTR Staff**
 - Avery Cook
 - Jon Snyder
- **UNOS Staff**
 - Lloyd Board
 - Brooke Chenault
 - Richard Hennings
 - Nadine Hoffman
 - Sevgin Hunt
 - Sara Langham
 - Lindsay Larkin
 - Meghan McDermott
 - Eric Messick
 - Lauren Mooney
 - Lauren Motley
 - Joel Newman
 - Kayla Temple
 - Kim Uccellini
 - Divya Yalgoori
 - Anne Zehner
- **Other Attendees**
 - Heather Bastardi
 - Bilal Mahmood
 - Rachel White