OPTN Living Donor Committee Decision Data Workgroup
Meeting Summary
October 03, 2024
Conference Call

Aneesha Shetty, MD, Chair

Introduction

The OPTN Living Donor Committee Decision Data Workgroup ("Workgroup") met via Cisco WebEx teleconference on 10/03/2024 to discuss the following agenda items:

1. **Recap of Goals and Last Workgroup Call**
2. **Survey Results and Discussion**

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

1. Recap of Goals and Last Workgroup Call

No decisions were made.

Summary of Presentation:

The Committee Chair reviewed the high-level project overview, including (1) Establishing a comprehensive of long-term risks and benefits that may be attributed to living donation; and (2) Analyzing any barriers to living donation.

This will be accomplished through collaboration with the SRTR's Living Donor Collective, using their kidney- and liver-related reasons for living donor declination. The OPTN will be expanding the current population of living donor data collection to not only those who donate, but also those individuals who pursue living donor evaluation but do not ultimately donate. The who do not donate will be classified as living donor candidates. Currently, data is only collected on living donors and not candidates that begin the evaluation process. This change will allow the OPTN to collect the donation decisions (and why they may not have donated) and continue to perform follow-up on living donors for the purposes of patient safety monitoring for the first two years. The SRTR will then use the initial OPTN information from pre-donation to the two-year mark to continue long-term follow-up through its Living Donor Collective data to follow living donor candidates and living donors, performing analyses on barriers to living donation and long-term outcomes of living donors versus living donor candidates.

This Workgroup is tasked with:

• Determine how to best collection donation decision data and how to best operationalize that collection at the center level

• Reviewing currently collected SRTR data elements for donation decision

• Helping to establish a workflow for the new data collection (reporting requirements, when to begin and end data collection timeframes, etc.)

• Serving as subject matter experts to Committee as needed

The Chair moved into the approach for data collection, which was previously discussed with the committee as, "Collecting some information on all candidates and collect specialized information related to donation decision reason code." This means some information would be collected for all living donor candidates and then, depending on reason(s) selected, more specialized information may be collected. Staff said that the Workgroup would be going through reasons (data elements to be collected) in this meeting. A member asked if pediatric recipients would be a special data set, as data for why someone may not donate to a child could be different than donation to an adult.

The Workgroup moved into the data collection survey results. The survey had been sent out to the workgroup prior to the meeting and prompted members to decide if each data element was important to the goals of the project, along with its method of collection.

2. Survey Results and Discussion

No decisions were made.

Summary of Presentation:

Staff reviewed overall feedback from the survey. Staff had asked if members had general thoughts about data entry burden. Members gave the following feedback:

- A general category of "other" was not recommended unless it would be a sub-drop down option from another data element.
- The form would need to be filled out by someone who is not clinical and data burdens and staff burdens should be kept in mind.

Staff reminded the workgroup that the number of data elements that the OPTN collects does not need to align with the number that SRTR collects.

Staff reviewed feedback regarding how many reasons were appropriate to collect. Answers ranged from 5 broad categories to 50 reasons. A member suggested 5 broad categories that could include sub-drop downs for more specific reasons. Staff suggested that a good starting place could be around 20 reasons, as future enhancements could be made to add more reasons as needed. A Data Advisory Committee (DAC) representative stated that broad categories can help alleviate data burden. The Workgroup agreed that having reasons categorized would simplify filling out the decision data form.

The Workgroup moved into reviewing survey feedback. The Workgroup was asked to review each data element and decide if it should be collect on its own, collected and combined with other reason(s), or not needed to collect/put into "other" category.

Summary of discussion:

Data Element	Collection method	Reasoning/Comments
Obesity	Collect on its own	Feedback included that this is a common declination reason. Members stated that body mass index (BMI) cutoff varies by transplant center. The workgroup agreed that it should be collected on its own.

Diabetes, type 2	Collect on its own	Members suggested collecting diabetes reasons in a similar manner to the Scientific Registry of Transplant Recipients, which would include "diabetes" with a drop-down into more specific categories. A member said that type 1 diabetes would already be screened out earlier in the living donation process. The workgroup agreed that type 2 diabetes should be collected on its own.
Possible current or future malignancy or cancer	Collect on its own	Members suggested rephrasing to "Active malignancy, concern for malignancy, and history of malignancy or cancer." Members said that this was an uncommon reason but important for understanding the long-term risk of cancer.
Unable to provide informed consent due to cognitive impairment, a developmental disability, or being too young	Combine with other reasons	Members suggested combining this reason with other psychosocial reasons. A DAC representative said that asking specific reasons in this instance could be a data burden.
Concern for future pregnancy and childbirth	Combine with other reasons	Members said this would be an uncommonly chosen reason, and it could be combined with other reasons. A member added that this reason could be collected on its own as there are medical comorbidities with pregnancy. The workgroup agreed to have continuing conversations about this.

Imaging and abnormality reasons – Liver Imaging and abnormality reasons - Kidney	Combine with other reasons. Staff suggestions: “Significant renal disease or insufficiency” “Significant hepatic disease” “Surgical complexity”	Members approved of “renal disease” and “hepatic disease” as a category. A member said that the staff-suggested reason of “surgical complexity” should include reasons that could impact future health, such as liver steatosis. Data entry members approved of combining reasons. A DAC representative asked if sub-drop downs would be mandatory. The workgroup agreed that the categories should be organ-specific and include sub-drop downs. Staff asked if the workgroup would like to include clinical information, such as lab values, in the sub-drop downs. Members said that data entry personnel may not be able to enter all types of specific data in the time frame needed. Members said some data fields may be easy to pull, though not all data fields would be necessary for all candidates.
Cardiovascular disease such as coronary artery disease, abnormal cardiac stress test, stroke, transient ischemic attack, abnormal carotid ultrasound or claudication	Collect on its own	Members said this is a high cause of mortality in the general population and it should be collected on its own. The workgroup agreed that the category should be kept broad.
High cholesterol, high triglycerides, or other lipid abnormalities	Collect on its own	A member said that this could be its own reason because a candidate could be turned down for reasons such as high cholesterol, independent of other medical issues. A DAC representative asked how

		high-cholesterol and high-triglycerides might be defined. A member said that this determination could be left to the programs.
Hypertension or poor blood pressure control	Collect on its own	Members said this is a common reason for declination, particularly for kidneys.
Lung disease	Collect on its own	Members said this could be collected on its own as it does not make sense to combine it with other reasons.
Hematologic abnormalities	Collect on its own	Members said this was already a broad category and would not need to be combined with other reasons. A member added that the Workgroup should be consistent with the wording of reasons, and that "abnormalities" should be used across reasons referencing physiological anomalies.
History of chronic pain from headaches, musculoskeletal problem or surgery	Not needed to collect or can be included in "other" category	This was found to be an uncommon reason that does not relate to the goals of data collection. The Committee Chair said that if this reason is referencing opioid use due to chronic pain, then the wording of the reason needs to be changed.
Substance abuse including alcohol, tobacco, marijuana, or narcotics	Collect and combine with other reasons	Members said this is a common contraindication, but it could be combined with other psychosocial reasons. A member said that the addition of many sub-drop downs, such as collecting specific substance

		abuse information, could be a burden on data entry.

Next steps:

The Workgroup will continue reviewing data elements.

Upcoming Meetings:

- 10/10/24

Attendance

- **Committee Members**
    - Aaron Ahearn
    - Aneesha Shetty
    - Amy Olsen
    - Jennifer Peattie
    - Katie Dokus
    - Julie Prigoff
    - Jennifer Peattie
    - Reza Saidi
    - Steve Gonzalez
    - Trysha Galloway
- **SRTR Representatives**
    - Katie Siegert
    - Caitlyn Nystedt
    - Avery Cook
- **HRSA Representatives**
    - Mesmin Germain
    - Allison Hutchings
    - Shannon Dunne
    - Arjun Naik
- **UNOS Staff**
    - Jamie Panko
    - Kieran McMahon
    - Laura Schmitt
    - Sam Weiss
    - Sara Langham