OPTN Living Donor Committee Decision Data Workgroup
Meeting Summary
September 5, 2024
Conference Call

Aneesha Shetty, MD, Chair

The OPTN Living Donor Decision Data Workgroup ("Workgroup") met via Cisco WebEx teleconference on 09/05/2024 to discuss the following agenda items:

1. **Scientific Registry of Transplant Recipients (SRTR) Data Elements Presentation**
2. **OPTN Living Donor Decision Data Elements Discussion**

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

1. SRTR Data Elements Presentation

No decisions were made.

Summary of Presentation:

The Chair briefly reviewed the data collection project, highlighting how the data elements from SRTR can be transferred over to the OPTN. Further, she discussed how the OPTN will create a workflow to collect this data. The SRTR went into their presentation on current SRTR decision data collection.

Figure 1: SRTR decision data on kidney-related reasons for declination

Reason for Not Donating	Count
Other Reason – Specify (free text)	142
Hypertension, blood pressure control or borderline high blood pressure	187
Low or borderline kidney function, -GFR or creatinine clearance	139
Decided against donation for undisclosed reason(s)*	135
Intended recipient underwent deceased donor transplant*	113
Risk of kidney stones	103
Candidate reluctant or ambivalent as indicated by missed appointments, failure to return calls, etc.	101

Image 2: SRTR decision data on liver-related reasons for declination

Reason for Not Donating	Count
Other Reason – Specify	50
Intended recipient underwent deceased donor transplant*	88
Inadequate liver volumes on imaging	46
Intended recipient became too ill for transplant or died	45
Decided against donation for undisclosed reason(s)*	45
Another living donor candidate was a better choice for other reasons	30
Donor liver steatosis on imaging or biopsy	32

The SRTR representative showed the SRTR kidney and liver data collection forms, which outlines the data elements that the Workgroup will review for the OPTN. The SRTR representative also reviewed the most common donation declination reasons for kidney and liver (listed above).

Summary of discussion:

A workgroup member asked if there were decision declination reasons chosen less than 5 times. The SRTR said they would be able to check this information. A member asked to clarify if this donation decision data is to be collected after evaluation, and it was confirmed that potential donors who reach this stage have already passed evaluation. The workgroup and SRTR discussed the time burden of completing donation decision collection forms, with SRTR stating this form usually takes an average of 9 minutes to complete. SRTR stated that 10 pilot programs took part in the Living Donor Collective program.

2. OPTN Living Donor Decision Data Elements Discussion

The workgroup reached consensus on 20 data elements listed below.

Summary of Presentation:

Staff presented options for data collection, such as combining or altering data element categories. The Chair also reminded the workgroup that they need to keep in mind the goal or finding barriers to living donation, as well as analyzing long-term outcomes.

Summary of discussion:

A member asked about recording decision data for each center involved in a paired kidney donation. OPTN research staff stated that decisions are currently only recorded for where their organ was donated even if they had a possible match previously. The workgroup reviewed each of the data elements. A member asked about whether some of this data should already be ruled out in evaluation, and members answered that there may be instances where not everything is ruled out before the donation decision stage.

- **Unable to provide informed consent -** The workgroup will continue discussing "unable to provide informed consent" to decide if this should be included as its own data element
- **Concern for future pregnancy and childbirth -** The workgroup agreed that "concern for future pregnancy and childbirth" is important and that people may be ruled out for donation if they are

planning to get pregnant in the near future. The workgroup considered this included in both medical and donor choice categories. They suggested that this be collected for both liver and kidney.

- **Possible current or future malignancy or cancer -** The workgroup recommended including "possible current or future malignancy or cancer," in the OPTN data collection. The group discussed if this should be medical-only or donation decision for future malignancy and agreed that this should be a medical reason. The workgroup discussed splitting up cancer and malignancy, and decided to continue discussing this. They suggested that this be collected for both liver and kidney.
- **Liver disease -** The workgroup recommended keeping "liver disease" and apply it to both liver and kidney donation.
- **Lung disease -** The workgroup recommended to keep lung disease and pare down the definition to include "lung disease" alone, as they stated that this is already inclusive. It will be collected for both liver and kidney.
- The workgroup chose to keep "cardiovascular disease" as-is, as they said it is already inclusive of necessary data collection, and suggested collecting for both liver and kidney.
- **Increased risk of bleeding or clotting -** For "increased risk of bleeding or clotting," the workgroup suggested to change this to "hematologic reasons," to be more inclusive of hematologic medical issues. They suggested this to be applied to both liver and kidney.
- **Various liver data elements -** The workgroup kept all liver-specific data elements as-is, including "vascular or biliary anatomic abnormalities on imaging," "inadequate liver volumes on imaging," "other unfavorable abnormalities on imaging," "donor liver steatosis on imaging or biopsy," and "other biopsy abnormalities," as they were noted to be the most common reasons for rejection of liver donation.
- **Diabetes -** For "diabetes," the workgroup recommended to split up into Type 1 and Type 2 because of where these reasons may be recorded in the evaluation process. Suggested for both kidney and liver.
- **Concern for risk of developing diabetes or prediabetes -** For "concern for risk of developing diabetes or prediabetes" the workgroup removed "metabolic syndrome," as this is covered in other elements. Suggested for both kidney and liver.
- **Obesity -** The workgroup left "obesity" as-is, suggested for both kidney and liver. The workgroup discussed possibly including BMI, but recognized the differences in obesity measurements between centers, and weight/BMI are collected at the registration phase.
- **Hypertension, prehypertension -** The workgroup suggested removing "borderline high blood pressure" from the data elements and changed it into "hypertension, prehypertension, or poor blood pressure control," and suggested this to be collected for both liver and kidney. The workgroup suggested this to expand blood pressure measurements to be collected if a center considers someone to have "poorly controlled blood pressure."
- **High cholesterol, high triglycerides, or other lipid abnormalities –** This element was left as-in and was suggested for both liver and kidney. The workgroup decided that there may be instances where "high triglycerides" may be present without other aspects of metabolic syndrome, so this element should be left alone.
- **Immunological incompatibility with the intended recipient including blood group incompatibility -** The workgroup removed "HLA antibodies" as this is a separate concept from blood group incompatibility. This was suggested for both liver and kidney.

Current SRTR Data Element	Suggested element for OPTN	Current SRTR Kidney and/or Liver Collection	Y/N suggestion for OPTN Inclusion
Unable to provide informed consent due to cognitive impairment, a developmental disability or being too young		Both	Not finished - revisit
Concern for future pregnancy and childbirth		Both	Y
Possible current or future malignancy or cancer		Both	Y
Liver disease		Both	Y
Lung disease including sarcoidosis, cysts, nodules, pulmonary hypertension	Lung disease	Both	Y
Cardiovascular disease such as coronary artery disease, abnormal cardiac stress test, stroke, transient ischemic attack, abnormal carotid ultrasound or claudication		Both	Y
Increased risk of bleeding or clotting, including low or high platelet counts or anemia	Hematologic reasons	Both	Y
Vascular or biliary anatomic abnormalities on imaging		Liver	Y
Inadequate liver volumes on imaging		Liver	Y
Other unfavorable anatomical abnormality on imaging		Liver	Y
Donor liver steatosis on imaging or biopsy		Liver	Y
Other biopsy abnormalities		Liver	Y
Diabetes, high A1C or high blood glucose	Diabetes, Type 2	Both	Y
Concern for risk of developing diabetes, prediabetes, metabolic syndrome	Concern for risk of developing diabetes, prediabetes	Both	Y
	Diabetes, Type 1	Both	Y
Obesity		Both	Y
Hypertension, prehypertension, poor blood pressure control or borderline high blood pressure	Hypertension, prehypertension, poor blood pressure control	Both	Y

High cholesterol, high triglycerides or other lipid abnormalities		Both	Y
Immunologic incompatibility with the intended recipient including blood group incompatibility or HLA antibodies	Immunologic incompatibility with the intended recipient including blood group incompatibility	Both	Y

Next steps:

The workgroup will continue these conversations at upcoming meetings.

Upcoming Meetings:

- September 19th, 2024

Attendance

- **Committee Members**
  - Aneesha Shetty
  - Scott Biggins
  - Nahel Elias
  - Gregory McKenna
  - Jennifer Peattie
  - Katie Dokus
  - Michael Chua
  - Tiffany Caza
  - Trysha Galloway
- **SRTR Representatives**
  - Avery Cook
  - Caitlyn Nystedt
  - Katie Siegert
- **HRSA Representatives**
  - Mesmin Germain
  - Ricardo Cale
- **UNOS Staff**
  - Jamie Panko
  - Kieran McMahon
  - Laura Schmitt
  - Meghan McDermott
  - Sam Weiss
  - Sara Langham
  - Sevgin Hunt