OPTN Living Donor Committee Decision Data Workgroup
Meeting Summary
December 19th, 2024
Conference Call

Aneesha Shetty, MD, Chair
Introduction

The OPTN Living Donor Committee Decision Data Workgroup ("Workgroup") met via Cisco WebEx teleconference on 12/19/2024 to discuss the following agenda items:

- Review Workflow
- Review and Discuss Mockup

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

1. Review Workflow

No decisions were made.

Summary of Presentation:

The Workgroup Chair reviewed the distinct roles of the Committee and also the Workgroup. The Workgroup is directly responsible for creating and updating the data collection forms, while the full committee will review the workgroup recommendations, improve informed consent, inform policy recommendations, and initiate future support for living donors.

The Chair reviewed the plan the for meeting, including discussion of big picture goals, review of a data collect form mockup, review of SRTR polit programs, and UNOS staff insight on computer systems.

The Chair also reviewed the Workflow document for living donors and living donor candidates, which was drafted at the Living Donor Committee in person meeting in September, 2024. The workflow is a detailed Microsoft Vision chart included in meeting materials.

2. Review and Discuss Mockup

Please see decisions in the chart below.

Summary of Presentation:

An OPTN data management staff member reviewed the mockup from the November workgroup meeting. First, a draft "Form B" to collect data on candidates who decide not to donate was reviewed, that was reviewed at the last meeting. It includes clinical information collection, too. SRTR as asked what they would like to include at the last meeting, too, too.

Summary of discussion:

Staff reviewed the data elements on Form B, noting that these elements will also be collected on Form A2, collected from candidates who proceed to donation.

Data Element	Decision	Discussion/Reasoning
Title on Form B: Clinical Information	Title should remain.	The committee agrees it is straightforward.
Medical History (General)	Add malignancy history and type. Revisit this, but Coronary Artery Disease (CAD) (Y/N) should be added as a question.	Staff asked if additional information should be collected. One member suggested history of malignancy. A member asked about family history, but that is collected in a different section. Members requested to include a question about gestational diabetes, since this is a different category than Type 1 or Type 2. A member requested to add a question to distinguish malignancy or skin cancer. It should capture melanoma, but should be distinguished from skin cancer. There is a monitoring report about exclusions and this group will hear a report at the next meeting. Should only "CAD" be included or should someone less broad about heart disease be included? If this is selected, the assumption is that this is a clinical diagnosis. The group agreed to look at this again for further discussion, but potentially have a follow up question about MI. It's possible a donor could be diagnosed with CAD after donation. Staff filling out these forms might not be able to distinguish for CAD and other heart disease.
Diabetes and Form Workflow	The Committee agreed on "Yes/No/Unknown", Type, and Treatment for sure. If yes, current or past, then type -ask	The data definition should be specific. A member requested that "GOP 1" be collected, as well, since it's not included in

	gestational or non gestational, then treatment. This data is needed if the candidate moves forward.	the diabetes options currently listed. The Chair said that diabetic candidates can be eligible as long as they are not on insulin. This was changed as a part of an effort two years ago, in which it was decided diabetics can donate as long as they are not on insulin. This is one reason to collect insulin related information.
		The Chair also like the idea of including insulin and non insulin hypoglycemic agent as an option (instead of orals) since this will cover new agents that may come out. It's important to capture past and current diabetic conditions, since candidates may not have this condition currently.
		Staff suggested there could be a "current" questionnaire and past history questionnaire. This could be a question asking "child" questions of current versus past. The Chair said it is important to know about current and past since a candidate could have had it and it could have be resolved.
		Staff recommends creating two data elements for this question. Collection of diabetes data is not consistent on all current forms.
		A member said the "past history" of diabetes question should only show up unless the first diabetes question is answered. It is important to know what patients/candidates were treated with in the past.

		A member pointed out this may difficult for staff to find past medical history on diabetes. It would be helpful to know but difficult to find. The Committee agreed on "Yes/No/Unknown", Type, and Treatment for sure. If yes, current or past, then type -ask gestational or non gestational, then treatment. This data is needed if the candidate moves forward. It is ok to select "unknown." Complications and control information could be too much and difficult to find, so won't be asked. A member asked if Form B must be filled out completely if the candidate does not move forward. If an evaluation starts, this should be filled out. Unclear how much of Form B is required to be filled out if candidate is lost. Labs are likely not relevant if candidate is lost. Only necessary information should be collected. It is important to focus on the efficiency of the form.
Filling out forms	Revisit.	A member asked about the format of the forms. Do all questions need to be answered "yes/no/unknown"? Staff explained that this is important to answer but the group currently just needs to decided what should be included. This can be revisited.
Hypertension	Ask: "Y/N/Unknown", if yes current/past, then treatment (pharmacological or not),	This can be formatted similar to diabetes: "Y/N/Unknown", if yes current/past, then

	controlled (Y/N). Number of meds will get captured in the Donor Decision question.	treatment (pharmacological or not), controlled (Y/N). Number of meds will get captured in the Donor Decision question. It is important to know if it is controlled or not controlled. It might be difficult for someone filling out the form to answer (controlled or not controlled).
		It is possible for the candidate is discovered to have it, they would be deferred or declined until blood pressure is under control.
		Staff reminded the Committee that this form is for all (those that follow though with donation or not). The medications can be captured in the "Donation Decision" data form.
Obesity	Y/N/Unknown	Weight and height be removed because it is already collected in medical history. A member said that many donors lose significant weight to donate, then gain it back. They are at higher risk of gaining weight after donation. How should this addressed? Unsure.
		Staff said there should be a definition and it should be what is standard and considered obese by BMI. If past weight loss is captured, there should be a timeframe associated. It is uncertain what timeframe is relevant and this might be too deep in the weeds.
		A member asks if this might be better to ask in the follow up since odds of gaining weight after donation will not

		necessarily exclude the candidate. Ask about obesity (Y/N) but don't ask about history until Donation Decision form. Add unknown, too.
Kidney Stone	Do not collect in Form B.	SRTR would like this data collection. The Committee agreed this is more relevant in the Donation Decision form but not needed as a baseline.

Data Element		Discussion/Reasoning
Diabetes (Y/N/Unknown)		
Hypertension (Y/N/Unknown)		
History of kidney stones (Y/N/Unknown)		
Family history of kidney disease (Y/N/Unknown)		

Upcoming Meetings:

- 1/16/25

Attendance

- **Committee Members**
  - Amy Olsen
  - Gregory McKenna
  - Jennifer Peattie
  - Katie Dokus
  - Michael Chua
  - Julie Prigoff
  - Stevan gonzalez
  - Tiffany Caza
  - Trysha Galloway
- **SRTR Representatives**
  - Katie Siegert
  - Caitlyn Nystedt
  - Avery Cook
- **HRSA Representatives**
  - Allison Hutchings
- **UNOS Staff**
  - Jamie Panko
  - Kieran McMahon
  - Sam Weiss
  - Laura Schmidt
  - Cole Fox
  - Lauren Mooney
  - Sara Rose Wells