OPTN Living Donor Committee
Living Donor Data Collection Workgroup
Meeting Summary
November 18, 2022
Conference Call

Introduction

The Living Donor Data Collection Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 11/18/2022 to discuss the following agenda items:

1. Living Donor Data Element Review

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The Workgroup reviewed data elements on the Living Donor Follow-up (LDF) forms.

Summary of discussion:

Data Element: Date of last contact or death (LDF)

A member asked whether "last contact" and "death" should be separate data elements. Staff noted that most living donors are alive at the 24 month follow-up period, so separating the data element would require transplant program staff to enter 'n/a' for a separate death field. Staff explained that combining "last contact" and "death" into one data element is to streamline data collection entry. The member supported the original intent. The member added that "date of last contact or death" should be close to the "most recent donor status" data element on the LDF form.

Another member noted that it is important that the data element is clear to those who are entering the data. The member agreed that a data element capturing the living donor's status should appear first, followed by the entry of the date that is associated with that status.

An SRTR representative asked for the percent of missing data for this data element. Staff noted that there is 100 percent completion for this data element.

Data Element: Most Recent Donor Status Since (LDF)

A member asked what the response "not seen" is intended to capture. The member noted the "not seen" response seems ambiguous. The member asked whether the "not seen" option may be drawing individuals away from entering a more specific response. The member suggested that "unknown" may be a better option than "not seen". The member stated that the response option "Living Donor status update by other health care facility" is similar to "not seen". The member explained that if a living donor status is provided by another health care facility, it means that the living donor was not seen at the transplant program.

An SRTR representative asked if adding an "other, specify" field would be helpful.

Another member suggested a response option should be added to address situations where a living donor is not loss-to-follow-up, but they are not seen for various reasons and the transplant program would like a LDF to generate in the future.

A member suggested that the response option "Living Donor status update by other health care facility" include mention to primary care physicians.

Another member stated a "lost-to-follow-up" response option is necessary, but it may not be necessary to distinguish between "no attempt to contact donor" and "unable to contact donor". The member stated the response options should be efficient and straightforward. The member acknowledged that having a response option that specifies "no attempt to contact donor" ensures transplant programs are doing their due diligence in living donor follow-up. The member added that it may not be a relevant response option anymore as the sentiment of the community in regards to living donor follow-up has improved and changed. Another member agreed.

A member asked if transplant programs are being reviewed for non-compliance with living donor follow-up. Another member noted that transplant programs are reviewed for compliance with living donor follow-up but may not be flagged.

A member stated that response options such as "living donor status update by other health care facility" are more important data as it aids in understanding the best way to follow-up with living donors post-donation.

Data Element: Attempts to contact (LDF)

Staff noted that this data is often not utilized as it is open text fields and difficult to analyze.

A member stated that if the data is not utilized, then it may not be a helpful data element to collect. The member suggested removal of this data element since the purpose of the data element is unclear and the data is not being utilized. Another member agreed. The member noted that if the data element does not help transplant programs contact or engage with living donors in the future, or help enroll living donors into the Living Donor Collective, then it is not useful.

Data Element: Kidney Complications since (LDF)

A member agreed that a discrete list of common kidney complications post-donation should be added to the response options.

An SRTR representative suggested considering this data element in the context of how the U.S. Food and Drug Administration (FDA) collects data for drug trials. The SRTR representative stated that the FDA collects data on whether there has been an adverse event, whether it was a serious adverse event, and whether the investigator believes it is related to the drug. The SRTR representative stated this methodology could be transferred to complication related data elements.

A member asked stated it will be difficult to define a "serious" adverse advent. The member suggested it may be more relevant to collect data on whether there was a hospitalization post-donation. An SRTR representative noted there the FDA has defined "serious adverse events".[1] The member asked whether a "serious adverse event" defined for drug trails would be applicable to the field of transplantation and living donation. Another member noted that determining a "serious adverse event" has a grey area that likely will require personal judgement. A member suggested that the list of possible "serious adverse events" be converted to response options as a way to ensure consistent data entry.

Another member noted that a lot of the potential response options for a "serious adverse event" as defined by the FDA are already collected on the LDF such as hospital readmission and death.

[1] U.S. Food and Drug Administration, *What is a Serious Adverse Event?.* Available at https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event.

Data Element: Liver Complications since (LDF)

Members agreed to keep this data element as is.

Data Element: Complications since (LDF)

Members agreed to keep this data element as is.

Next steps:

The Workgroup will continue reviewing living donor data elements.

Upcoming Meeting

- December 16, 2022 (teleconference)
- January 20, 2022 (teleconference)

Attendance

- **Workgroup Members**
  - Angele Lacks
  - Jesse Schold
  - Nahel Elias
  - Macey Levan
  - Paul MacLennan
  - Stevan Gonzalez
  - Vanessa Arriola
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
  - Mesmin Germain
  - Shannon Dunne
- **SRTR Staff**
  - Bert Kasiske
  - Katie Siegert
- **UNOS Staff**
  - Cole Fox
  - James Alcorn
  - Jen Wainright
  - Kim Uccellini
  - Lindsay Larkin
  - Meghan McDermott
  - Samantha Weiss