

OPTN Living Donor Committee Decision Data Workgroup

Meeting Summary

October 24, 2024

Conference Call

Aneesha Shetty, MD, Chair

Introduction

The OPTN Living Donor Committee Decision Data Workgroup (“Workgroup”) met via Cisco WebEx teleconference on 10/24/2024 to discuss the following agenda items:

- 1. Overall Goals Discussion**
- 2. Control Group Discussion**
- 3. Data Advisory Committee (DAC) Feedback and Discussion**
- 4. Revisit Timeline Approach**

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

1. Overall Goals Discussion

No decisions were made.

Summary of Presentation:

Workgroup leadership presented the project overview and project goals. The Workgroup Chair emphasized that the workgroup is focusing on collecting donation decision data to permit and better understanding of access to living donation and inform solutions to reduce potential barriers. The Workgroup Chair mentioned that the data from this project can guide future projects to further analyze donation barriers. The Workgroup Chair also stated that long-term follow-up with donors is important, and the control group could cultivate quality long-term follow-up. However, she also mentioned that there should be a balance between collecting an appropriate level of detail on the control group and limiting the data burden for transplant program so as to not impede policy implementation for transplant programs.

Summary of discussion:

A member stated that understanding the “why” of a declination is the goal of gathering this data. A Data Advisory Committee (DAC) member stated that the gathering of data from pre-existing collections, such as selection committees, would cut down on the need for transplant programs to build their own ways of decision data collection. Research staff stated that it is important to collect medical decision data, as these are purposeful barriers meant to protect potential donors and recipients. Though, the Workgroup Chair stated, there are some medical conditions that are no longer a barrier, and educational materials could be created if decision data collection reveals them to be a large declination reason.

2. Control Group Discussion

No decisions were made.

Summary of Presentation:

Research staff asked the members how a control group could help the Workgroup achieve its project goals of understanding living donation and ensuring living donor safety. Staff presented two types of barriers to becoming a living donor: unintentional (such as logistical barriers to completing evaluation) and intentional (medically necessary barriers for patient safety). The Workgroup is focusing on alleviating unintentional barriers that would disallow an otherwise willing and healthy potential candidate from donating. Staff showed examples of how donor safety could be assessed long-term for donors vs. the control group. They also mentioned that the Workgroup needs to consider how they can design a study to answer research questions that meet the goals of the project. Further, they would need to consider data needs and practicality of data collection.

Summary of discussion:

A member mentioned that collecting both qualitative and quantitative data would be necessary for project goals. The Workgroup Chair continued that the data form could have qualitative data fields with quantitative dropdowns. The Chair asked if this type of data collection would be enough information to meet project goals. They also asked if baseline data elements should be collected for all candidates. A DAC member stated that the importance of discrete values may depend on the qualitative element, such as a stable value like BMI versus a changing value like blood pressure. A member replied that generic collection of data for everyone can help collect all declination factors.

The Workgroup reviewed the workflow as a reminder of touchstones of evaluation.

3. Data Advisory Group (DAC) Feedback and Discussion

No decisions were made.

Summary of Presentation:

The Workgroup Chair discussed updates from a meeting with DAC leadership where they talked about goal alignments and data collection burden. DAC had stated that they support the project but believed that it needed more time for quality data collection planning. DAC said that data must be both mappable and easily accessible for coordinators entering data.

Summary of discussion:

A transplant administration member said that not having standard selection criteria can lead to subjectivity in interpreting data. The Chair agreed that data elements should only have a quantitative aspect if its interpretation would be clear for both those entering and analyzing data. The chair said that guidance for documenting data could be helpful for anyone collecting data who may not have a non-clinical background.

4. Revisit Timeline Discussion

The Workgroup affirmed the extended project timeline.

Summary of Presentation:

The Workgroup Chair reviewed the timeline, showing that the proposal still needs decisions made in the areas of workflow, data elements for collection, policy language, monitoring plan, and transitional and educational plans. The Workgroup discussed possible timeline plans, which could include pushing for January timeline, going out for request for feedback, or pushing back the timeline to the following public comment cycle. The workgroup recognized that the Committee originally recommended pushing for January, while also acknowledging that winter or summer public comment would not change the Office of Management and Budget submission time.

Summary of discussion:

The Workgroup Chair said that request for feedback might not be the best option given that the proposal still has areas that are undeveloped. The Workgroup agreed that the timeline should be pushed back because of the number of items still needing discussion, such as which data elements for collection, methods of collection, and overall feasibility and quality of data.

Next steps:

The Committee and Workgroup will continue the proposal on an extended timeline past January 2025.

Upcoming Meetings:

- 11/13/24

Attendance

- **Committee Members**
 - Aaron Ahearn
 - Aneesha Shetty
 - Amy Olsen
 - Michael Chua
 - Jennifer Peattie
 - Katie Dokus
 - Julie Prigoff
 - Steve Gonzalez
 - Obi Ekwenna
 - Trysha Galloway
- **SRTR Representatives**
 - Katie Siegert
 - Caitlyn Nystedt
 - Avery Cook
- **HRSA Representatives**
 - Mesmin Germain
 - Nawraz Shawir
- **UNOS Staff**
 - Jamie Panko
 - Kieran McMahon
 - Laura Schmitt
 - Sam Weiss
 - Sara Langham
 - Cole Fox
 - Lindsay Larkin
 - Lauren Mooney
 - Sara Rose Wells