

**OPTN Executive Committee
Meeting Summary
September 8, 2023
Webex**

Dianne LaPointe Rudow, ANP-BC, DNP, FAAN, Chair

Introduction

The OPTN Executive Committee met via Webex on 09/08/2023 to discuss the following agenda items:

1. Welcome and Announcements
2. Change to Patient Race and Ethnicity Data Collection to Align with OMB Data Collection*
3. Whistleblower Protection Policy*
4. Strategic Planning

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

1. Welcome and Announcements

Dianne LaPointe Rudow, Chair of the Executive Committee, welcomed the committee to the meeting and presented the agenda.

2. Change to Patient Race and Ethnicity Data Collection to Align with OMB Data Collection*

Contractor staff presented a mini-brief to change patient race and ethnicity data collection to align with Office of Management and Budget (OMB) data collection. The Department of Health and Human Services (HHS) has directed the OPTN to align race and ethnicity data collection with OMB data collection standards. Consistency with OMB standards for race and ethnicity will allow OPTN data sets to align more accurately with alternate data sets, including federal data sets. This alignment will improve the ability to report on equity metrics in organ donation and transplantation by separating out the data collection variables for race and ethnicity. The purpose of the mini brief is to align policy language with the required data collection changes per the HHS directive.

The proposal will align various sections of policy language to allow for the data collection separation of race and ethnicity. Alignment will include adding race in addition to ethnicity where only ethnicity appears in policy language and, in one instance, clarifying race as the appropriate data point instead of ethnicity. Updated OPTN policies include:

- 2.11: Required Deceased Donor Information
- 5.4.A: Nondiscrimination in Organ allocation
- 8.4.B: Deceased Donor Classifications
- 13.6.A: Requirements for Match Run Eligibility for Candidates
- 13.6.B: Requirements for Match Run Eligibility for Potential KPD Donors

An example of the data collection form was shared with the committee. Members will report both race and ethnicity for all deceased donors, candidates, and living donors in all applications within the OPTN Computer System. If race and ethnicity are unknown or not reported, options will appear for members to choose "ethnicity not reported" or "race not reported". The OPTN is planning to implement the data

collection changes required by the HHS directive on September 14, 2023, into the OPTN Computer System.

Summary of Discussion:

The committee discussed the importance of ensuring OPTN data collection matches other federal data collection standards. The committee also discussed the importance of reporting a patient's race and ethnicity. The committee discussed how the database will allow physicians to choose multiple options within the system to account for mixed-race patients.

Vote:

The Executive Committee approved the following resolution:

RESOLVED, that the changes in *Policies 2.11: Required Deceased Donor Information, 5.4.A: Nondiscrimination in Organ Allocation, 8.4.B: Deceased Donor Classifications, 13.6.A: Requirements for Match Run Eligibility for Candidates, and 13.6.B: Requirements for Match Run Eligibility for Potential KPD Donors*, as set forth in the materials distributed on September 6, 2023 are hereby approved, effective September 14, 2023.

3. Whistleblower Protection Policy*

Rebecca Murdock, Senior Policy Counsel, presented the draft whistleblower protection policy to the committee. Ms. Murdock shared a timeline of the progress to date with the committee. On June 25, 2023, the Executive Committee approved the development of a policy, with the goals of including a strong statement on encouraging different viewpoints, that no retaliation will be permitted for the expression of those viewpoints, and to codify into OPTN policy existing processes for reporting concerns about suspected violations of law or ethics. On August 14, the committee reviewed the draft policy language and were encouraged to share any feedback they had on the policy.

Ms. Murdock explained that OPTN Policy 1.6, Whistleblower Protection Policy, will serve many different roles in protecting whistleblowers. The policy will establish a code of conduct to:

- Raise concerns against the OPTN,
- Have the OPTN publish a statement against retaliation,
- Establish procedure for annual reporting for the OPTN Executive Director to the OPTN President,
- Act in "good faith",
- Protect the confidentiality of whistleblowers.

Ms. Murdock shared the updates that have been made to the draft policy since the committee met on August 14. These updates include adding language to 1.6.B on the reporting procedure for reports involving the OPTN Executive Director, adding language to 1.6.F on how to handle reports that grant the OPTN Executive Director or OPTN President discretion to secure additional expertise to aid investigation, and updating policy language for consistency.

Implementation of the policy would include an update on the OPTN website and a notification to the OPTN community.

The committee voted on the policy as written and would then decide whether the policy required public comment.

Summary of Discussion:

The committee discussed whether the policy was subject to public comment. Because the changes to the policy are considered administrative changes for the OPTN's own regulation, there was conversation

around whether this warrants public comment. Ms. Murdock explained that the mini-brief on the policy change outlines why the Whistleblower Protection Policy does not necessitate public comment. She shared the bylaw language in OPTN Bylaw Section 11.1(A), regarding why the policy would not require public comment.

The committee discussed whether the policy addressed the concerns that have been raised by the transplant community that the OPTN welcomes dissenting opinions. A committee member asked the group to consider whether the policy was going to serve its intended purpose to mitigate these concerns.

The committee, along with representatives from HRSA, questioned whether the policy development process was sufficiently transparent to ensure agreement on whether the proposal is subject to public comment prior to the vote on the policy. Dr. LaPointe Rudow asked the committee to consider whether it was more important to submit the policy for public comment, or to show the community the OPTN's commitment to handling whistleblowing claims. She commented on the importance of not delaying implementation of this policy by requesting public comment and implementing it as soon as possible.

Representatives from HRSA stated that they were unable to provide a decision on whether the bylaw change requires public comment. The representative from HRSA stated that they were unaware of the decision the committee had come to, based on prior meetings. The representative stated that the language of the OPTN Final Rule takes precedence over any language within the OPTN Bylaws.

Vote:

Following discussion, the Executive Committee approved the following resolution:

RESOLVED, that the creation of *Policy 1.6: Whistleblower Protection Policy*, as set forth in the materials distributed on September 6, 2023, is hereby approved, pending notice and implementation.

Next Steps:

The whistleblower policy will undergo further review from HRSA to determine if the policy is required to go through the public comment process.

4. Strategic Planning

Dianne LaPointe Rudow presented on the National Organ Transplant Act (NOTA) and the OPTN Vision and Goals to help frame the committee's conversation on strategic planning. Dr. LaPointe Rudow emphasized the importance of creating a strategic plan that is broad enough to adapt to impending changes throughout the OPTN.

Contractor staff presented to the committee and asked the committee to focus on refining themes that formed from conversations and feedback during regional meetings, Board meetings, and Executive Committee review. The objective of the meeting was for the committee to focus on taking the themes and refining them to create goals. The top three themes were consistent between the Executive Committee and virtual regional meeting attendees. The top three themes were:

- Improve allocation efficiency
- Increase donors and available organs for use
- Increase transplants

Contractor staff presented the feedback that each theme received during earlier Executive Committee meetings and regional meetings. The committee was asked to consider three refined goals based on the feedback received. The refined goals were:

- Increase organ acceptance
- Decrease organ non-utilization
- Increase efficiency and improve allocation

Dr. LaPointe Rudow asked the committee to consider whether these refined goals were encompassing of the strategic plan and to consider if there is anything missing in these refined goals.

Summary of Discussion:

The committee discussed how patients would be involved in the strategic plan. The committee discussed having a patient specific goal, incorporating patients into each of the strategic goals, or to include an introductory statement to the strategic plan on how each goal is beneficial to patients.

The committee discussed the importance of including all key stakeholder groups within the strategic plan, including patients. One committee member suggested tactics within each goal on how key stakeholder groups would benefit from the strategic plan. The committee agreed that how the strategic plan is messaged to the community is crucial. The committee discussed the importance of having all stakeholders aligned on the goals of the transplant community.

Next Steps:

The committee will meet in-person on October 10 to further refine the goals and develop objectives and metrics for each goal.

The meeting adjourned.

Upcoming Meetings

- September 22, 2023
- October 10, 2023
- November 6, 2023

Attendance

- **Committee Members**
 - Andrea Tietjen
 - Dianne LaPointe Rudow
 - Ginny McBride
 - Jerry McCauley
 - Jim Sharrock
 - Linda Cendales
 - Manish Gandhi
 - Melissa McQueen
 - Richard Formica
 - Silas Norman
 - Valinda Jones
 - Wendy Garrison
- **HRSA Representatives**
 - Adrienne Goodrich-Doctor
 - Christopher McLaughlin
 - Daniel Thompson
 - Frank Holloman
- **UNOS Staff**
 - Anna Messmer
 - James Alcorn
 - Julie Nolan
 - Lauren Mauk
 - Maureen McBride
 - Morgan Jupe
 - Rebecca Murdock
 - Susie Sprinson
 - Tony Ponsiglione
 - Trish Jasion