OPTN

Notice of OPTN Policy Change

Align OPTN Policy to Support Changes to Race and Ethnicity Data Collection

Policies Affected:	*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
Executive Committee Approved:	**September 8, 2023**
Effective Date:	**September 14, 2023**

Purpose of Change

In a letter to the Organ Procurement and Transplantation Network (OPTN), the Department of Health and Human Services (HHS) directed the OPTN to align race and ethnicity data collection to the Office of Management and Budget (OMB) data collection Standard.[1] Currently, the OPTN collects Ethnicity/Race in a single data field, in which the response options include many different types of ethnic and racial categories. While this practice meets the minimum OMB standards, it does not allow this information to be linked to other data sets, including federal datasets (e.g., United States Census Bureau). Implementing these changes will improve the ability to report on equity metrics in organ donation and transplantation and to analyze and compare OPTN data to comparable federal data. The proposed policy changes will support these data collection changes by instituting a two separate questions format that will separate out ethnicity data collection, now defined as Hispanic/Latino or non-Hispanic/Latino, from race data collection.

While compliance with this directive is mostly done through operational changes in the system, the policy changes are necessary to support the implementation of the required data changes.

Purpose of Change

This policy proposal is not sponsored by a specific Committee but has been undertaken in response to HHS's directive to the OPTN requesting the proposed changes. Several Committees including the Data Advisory and Executive Committee have conducted a comprehensive review and analysis regarding the proposed policy changes.

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[1] Christoper McLaughlin to Jerry McCauley and Brian Shepard, September 8, 2022, Department of Human and Health Services.

Summary of Changes

To align with the OMB Standard, two separate questions will be used to separate data collection for ethnicity, now defined as Hispanic/Latino or non-Hispanic/Latino, from race data collection. To reflect these data collection changes, language to the following OPTN policies must be updated. Policy language changes include adding "race" to all areas where "ethnicity" is articulated in policy and, in one instance, clarifying that the data used will be "race" not "ethnicity" (*Policy 8.4.B Deceased Donor Classifications*).

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*

Implementation

The OPTN has coordinated these data collection changes with software vendors supporting the member organizations and aligned with HRSA on an orchestrated release in September. The policy changes will take effect on September 14, 2023, at the same time as the data changes.

Affected Policy Language

New language is underlined (underline) and language that is deleted is struck through (~~example~~).

2.11 Required Deceased Donor Information

The host OPO must report to the OPTN upon receipt *all* of the following information for each potential deceased donor:

1.   Age
1.   Diagnosis (or cause of brain death)
2.   Donor behavioral and social history
3.   Donor management information
4.   Donor medical history
5.   Donor evaluation information to include all laboratory testing, radiologic results, and injury to the organ
6.   Ethnicity
8.   Race
~~8~~9.   Height
~~9~~10.   Organ anatomy and recovery information
~~10~~11.   Sex
~~11~~12.   All vital signs, including blood pressure, heart rate, and temperature
~~12~~13.   Weight
~~13~~14.   SARS-CoV-2 (COVID-19) testing status. If COVID-19 testing was performed, the host OPO must report to the OPTN the date and time, type of specimen, testing method, and results.

The potential transplant program team must have the opportunity to speak directly with responsible onsite OPO donor personnel to obtain current information about the deceased donor's physiology.

5.4.A   Nondiscrimination in Organ Allocation

A candidate's citizenship or residency status in the United States must not be considered when allocating deceased donor organs to candidates for transplantation. Allocation of deceased donor organs must not be influenced positively or negatively by political influence, national origin, ethnicity, race, sex, religion, or financial status.

8.4.B   Deceased Donor Classifications

Kidneys from deceased donors are classified according to the Kidney Donor Profile Index (KDPI). The KDPI score is derived directly from the Kidney Donor Risk Index (KDRI) score. The KDPI is the percentage of donors in the reference population that have a KDRI less than or equal to this donor's KDRI. The donor characteristics used to calculate KDRI are provided in *Table 8-5* below.

Table 8-5: KDRI Factors

This deceased donor characteristic:	Applies to:	KDRI score component:
Age (integer years)	All donors	0.0128*(age-40)
	Donors with age < 18	-0.0194*(age-18)
	Donors with age > 50	0.0107*(age-50)
~~Ethnicity~~ Race	African American donors	0.1790
Creatinine (mg/dL)	All donors	0.2200*(creatinine - 1)
	Donors with creatinine > 1.5	-0.2090*(creatinine -1.5)
History of Hypertension	Hypertensive donors	0.1260
History of Diabetes	Diabetic donors	0.1300
Cause of Death	Donors with cerebrovascular accident as cause of death	0.0881
Height (cm)	All donors	-0.0464*(height -170) / 10
Weight (kg)	All donors with weight < 80 kg	-0.0199*(weight - 80) / 5
Donor type	DCD donors	0.1330
HCV status	HCV positive donors	0.2400

To calculate KDRI, follow these steps:

1. Sum each of the applicable KDRI score components in *Table 8-5*
2. Apply the antilog (base e) function to this sum

3. Divide the KDRI by the median KDRI value of the most recent donor reference population
4. Determine the KDPI using the OPTN's KDRI-to-KDPI mapping table

The KDPI score is rounded to the nearest integer.

The KDPI used for allocation is based on the most recent values of donor characteristics reported to the OPTN before executing a match run.

The reference population used to determine the KDRI-to-KDPI mapping is reviewed annually by the Kidney Transplantation Committee and updated by the OPTN on or before June 1 of each calendar year.

13.6.A Requirements for Match Run Eligibility for Candidates

The OPTN KPD program will only match candidates who comply with *all* of the following requirements:

1. The candidate's transplant hospital must comply with *Policies 5.6.A: Receiving and Reviewing Organ Offers, 5.7: Organ Check-In, and 5.8: Pre-Transplant Verification*
2. The candidate's transplant hospital must complete the informed consent process according to *Policy 13.3: Informed Consent for KPD Candidates*
3. The candidate's transplant hospital must submit *all* the information for these required fields to the OPTN Contractor:

    a. Candidate details, including *all* of the following:
       - Last name
       - First name
       - SSN
       - Date of birth
       - Gender
       - Ethnicity
       - Race
       - ABO
       - Whether the candidate has signed an agreement to participate in the OPTN KPD program
       - Whether the candidate has signed a release of protected health information
       - Whether the candidate is a prior living donor
       - KPD status: active, inactive or removed. A candidate must have current active status in the OPTN KPD program to be eligible for a match run.

    b. Candidate choices, including *all* of the following
       - Whether the candidate would be willing to travel, and, if so, the transplant hospitals to which a candidate would be willing to travel or the distance the candidate is willing to travel
       - Whether the candidate is willing to accept a shipped kidney, and, if so, from which transplant hospitals the candidate would be willing to accept a shipped kidney
       - Minimum and maximum acceptable donor age
       - Minimum acceptable donor creatinine clearance or glomerular filtration rate (GFR)

- Maximum acceptable donor BMI
- Maximum acceptable systolic and diastolic blood pressure
- Whether the candidate is willing to accept a hepatitis B core antibody positive KPD donor, a CMV positive KPD donor, and an EBV positive KPD donor
- Whether the candidate would be willing to accept a left kidney, right kidney, or either kidney

    c. Candidate HLA as defined in *Policy 13.5.A: Histocompatibility Requirements for KPD Candidates*

4. The candidate must have at least one active and eligible potential KPD donor registered in the OPTN KPD program
5. The candidate's transplant hospital must submit a response for all previous match offers for the candidate in the OPTN KPD program, including reasons for refusing offers
6. The candidate must not be in a pending exchange in the OPTN KPD program

13.6.B Requirements for Match Run Eligibility for Potential KPD Donors

The OPTN KPD program will only match potential KPD donors that comply with *all* of the following requirements:

1. The transplant hospital registering the potential KPD donor must perform blood typing and subtyping as required by *Policy 14.5: Living Donor Blood Type Determination and Reporting* with the following modifications:

    a. The transplant hospital registering the potential KPD donor must report the potential KPD donor's actual blood type to the OPTN Contractor

    b. A qualified health care professional, other than the qualified health care professional who initially reported the potential KPD donor's blood type to the OPTN Contractor, must compare the blood type from the two source documents, and separately report the potential KPD donor's blood type to the OPTN Contractor

    c. The potential KPD donor is not eligible for a KPD match run until the transplant hospital verifies and reports two identical blood types

2. The transplant hospital registering the potential KPD donor must complete the informed consent process according to *Policy 13.4: Informed Consent for KPD Donors.*
3. The transplant hospital registering the potential KPD donor must complete the evaluation process according to *Policy 14: Living Donation*.
4. The transplant hospital registering the potential KPD donor must submit the information for the required fields below to the OPTN Contractor:

    a. Donor details, including *all* of the following:
- Last name
- First name
- SSN
- Date of birth
- Gender
- Ethnicity

- Race
- ABO
- Height and weight
- Whether the potential KPD donor is a non-directed donor or a paired donor
- If the potential KPD donor is a paired donor, the KPD Candidate ID of the paired candidate and the potential KPD donor's relationship to the candidate
- Whether the potential KPD donor has signed an agreement to participate in the OPTN KPD program
- Whether the potential KPD donor has signed a release of protected health information
- Whether the potential KPD donor has signed an informed consent as required in policy
- Whether the potential KPD donor has undergone all evaluations as required in *Policy 14: Living Donation*
- Whether the potential KPD donor has had all cancer screenings as required in *Policy 14: Living Donation*
- KPD status: active, inactive or removed. A donor must have current active status in the OPTN KPD program to be eligible for a match run.

b. Clinical information, including *all* of the following:
- The number of anti-hypertensive medications the potential KPD donor is currently taking
- Systolic and diastolic blood pressure with date (either 24-hour monitoring or two measurements)
- Creatinine clearance or glomerular filtration rate (GFR), date, and method
- Anti-CMV, EBV, HbsAg, and Anti-HbcAb serology results

c. Donor choices, including *all* of the following:
- Whether the potential KPD donor would be willing to travel, and, if so, the transplant hospitals to which the potential KPD donor would be willing to travel or the distance the donor is willing to travel
- Whether the potential KPD donor is willing to ship a kidney
- Whether the potential KPD donor is willing to donate a left kidney, right kidney, or either kidney
- Whether the KPD candidate-donor pair and the transplant hospital are willing to participate in a three-way exchange or a donor chain
- Whether the potential KPD donor and the transplant hospital are willing for the potential KPD donor to be a bridge donor

d. Donor HLA as defined in *Policy 13.5.C: HLA Typing Requirements for OPTN KPD Donors*

5. The potential KPD donor must be paired to an active and eligible candidate registered in the OPTN KPD program or be a non-directed donor
6. The transplant hospital registering the potential KPD donor must submit a response for all previous match offers for the potential KPD donor in the OPTN KPD program, including reason for refusing offers
7. The potential KPD donor must not be in a pending exchange in the OPTN KPD program

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