

Mini-Brief

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

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Contents

Background	1
Purpose	1
Proposed Changes	1
Implementation	2
Policy Language	3

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

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

Executive Committee Approval:

September 8, 2023

Effective Date:

September 14, 2023

Background

Currently, OPTN data collection combines race and ethnicity in a single variable. 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). In a letter to the Organ Procurement and Transplantation Network (OPTN), the Department of Health and Human Services directed the OPTN to align race and ethnicity data collection to the Office of Management and Budget (OMB) data collection Standard.¹ To do so, the OPTN will separate out ethnicity data collection, now defined as Hispanic/Latino or non-Hispanic/Latino, from race data collection. 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.

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

Purpose

The purpose of these proposed changes is to modify OPTN policies to support the required changes to OPTN data collection.

Proposed Changes

To align with the OMB Standard, OPTN data collection will separate the 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:

¹ McLaughlin, Chris. (September 8, 2022). [Letter to the OPTN directing the OPTN to take actions regarding data collection practices].

- *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 transplant community was notified of the federal mandate to make the changes to OPTN data collection on March 29, 2023.² If adopted, the policy changes will take effect on September 14, 2023 at the same time as the data changes. The OPTN will provide members and the broader community with a notice of implementation of these policy language changes along with the race and ethnicity data collection changes.

² "OPTN Data Collection Changes Coming Sept. 14." OPTN Computer System—System Notice, March 29, 2023.

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~)

1 **2.11 Required Deceased Donor Information**

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

- 4
- 5 1. Age
- 6 2. Diagnosis (or cause of brain death)
- 7 3. Donor behavioral and social history
- 8 4. Donor management information
- 9 5. Donor medical history
- 10 6. Donor evaluation information to include all laboratory testing, radiologic results, and injury to
- 11 the organ
- 12 7. Ethnicity
- 13 8. Race
- 14 ~~89.~~ Height
- 15 910. Organ anatomy and recovery information
- 16 ~~1011.~~ Sex
- 17 ~~1112.~~ All vital signs, including blood pressure, heart rate, and temperature
- 18 ~~1213.~~ Weight
- 19 ~~1314.~~ SARS-CoV-2 (COVID-19) testing status. If COVID-19 testing was performed, the host OPO must
- 20 report to the OPTN the date and time, type of specimen, testing method, and results.

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

24 **5.4.A Nondiscrimination in Organ Allocation**

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

30 **8.4.B Deceased Donor Classifications**

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32 Kidneys from deceased donors are classified according to the Kidney Donor Profile Index (KDPI). The
33 KDPI score is derived directly from the Kidney Donor Risk Index (KDRI) score. The KDPI is the percentage
34 of donors in the reference population that have a KDRI less than or equal to this donor's KDRI.

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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)
<u>Ethnicity Race</u>	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

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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.

56 13.6.A Requirements for Match Run Eligibility for Candidates

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

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

65 a. Candidate details, including *all* of the following:

- 66 • Last name
 67 • First name
 68 • SSN
 69 • Date of birth
 70 • Gender
 71 • Ethnicity
 72 • Race
 73 • ABO
 74 • Whether the candidate has signed an agreement to participate in the OPTN KPD
 75 program
 76 • Whether the candidate has signed a release of protected health information
 77 • Whether the candidate is a prior living donor
 78 • KPD status: active, inactive or removed. A candidate must have current active status
 79 in the OPTN KPD program to be eligible for a match run.
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81 b. Candidate choices, including *all* of the following

- 82 • Whether the candidate would be willing to travel, and, if so, the transplant hospitals
 83 to which a candidate would be willing to travel or the distance the candidate is
 84 willing to travel
 85 • Whether the candidate is willing to accept a shipped kidney, and, if so, from which
 86 transplant hospitals the candidate would be willing to accept a shipped kidney
 87 • Minimum and maximum acceptable donor age
 88 • Minimum acceptable donor creatinine clearance or glomerular filtration rate (GFR)
 89 • Maximum acceptable donor BMI
 90 • Maximum acceptable systolic and diastolic blood pressure
 91 • Whether the candidate is willing to accept a hepatitis B core antibody positive KPD
 92 donor, a CMV positive KPD donor, and an EBV positive KPD donor
 93 • Whether the candidate would be willing to accept a left kidney, right kidney, or
 94 either kidney

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

- 97 4. The candidate must have at least one active and eligible potential KPD donor registered in the
 98 OPTN KPD program

- 99 5. The candidate’s transplant hospital must submit a response for all previous match offers for
 100 the candidate in the OPTN KPD program, including reasons for refusing offers
 101 6. The candidate must not be in a pending exchange in the OPTN KPD program
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103 **13.6.B Requirements for Match Run Eligibility for Potential KPD Donors**

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

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- 107 1. The transplant hospital registering the potential KPD donor must perform blood typing and
 108 subtyping as required by *Policy 14.5: Living Donor Blood Type Determination and Reporting*
 109 with the following modifications:
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 - 111 a. The transplant hospital registering the potential KPD donor must report the potential
 112 KPD donor’s actual blood type to the OPTN Contractor
 - 113 b. A qualified health care professional, other than the qualified health care professional
 114 who initially reported the potential KPD donor’s blood type to the OPTN Contractor,
 115 must compare the blood type from the two source documents, and separately report
 116 the potential KPD donor’s blood type to the OPTN Contractor
 - 117 c. The potential KPD donor is not eligible for a KPD match run until the transplant
 118 hospital verifies and reports two identical blood types
 119
 - 120 2. The transplant hospital registering the potential KPD donor must complete the informed consent
 121 process according to *Policy 13.4: Informed Consent for KPD Donors*.
 - 122 3. The transplant hospital registering the potential KPD donor must complete the evaluation
 123 process according to *Policy 14: Living Donation*.
 - 124 4. The transplant hospital registering the potential KPD donor must submit the information for the
 125 required fields below to the OPTN Contractor:
 126
 - 127 a. Donor details, including *all* of the following:
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 - 129 • Last name
 - 130 • First name
 - 131 • SSN
 - 132 • Date of birth
 - 133 • Gender
 - 134 • Ethnicity
 - 135 • Race
 - 136 • ABO
 - 137 • Height and weight
 - 138 • Whether the potential KPD donor is a non-directed donor or a paired donor
 - 139 • 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
 - 140 • Whether the potential KPD donor has signed an agreement to participate in the
 OPTN KPD program
 - 141 • Whether the potential KPD donor has signed a release of protected health
 142 information
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- 144 • Whether the potential KPD donor has signed an informed consent as required in
- 145 policy
- 146 • Whether the potential KPD donor has undergone all evaluations as required in
- 147 *Policy 14: Living Donation*
- 148 • Whether the potential KPD donor has had all cancer screenings as required in *Policy*
- 149 *14: Living Donation*
- 150 • KPD status: active, inactive or removed. A donor must have current active status in
- 151 the OPTN KPD program to be eligible for a match run.
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- 153 b. Clinical information, including *all* of the following:
- 154 • The number of anti-hypertensive medications the potential KPD donor is currently
- 155 taking
- 156 • Systolic and diastolic blood pressure with date (either 24-hour monitoring or two
- 157 measurements)
- 158 • Creatinine clearance or glomerular filtration rate (GFR), date, and method
- 159 • Anti-CMV, EBV, HbsAg, and Anti-HbcAb serology results
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- 161 c. Donor choices, including *all* of the following:
- 162 • Whether the potential KPD donor would be willing to travel, and, if so, the
- 163 transplant hospitals to which the potential KPD donor would be willing to travel or
- 164 the distance the donor is willing to travel
- 165 • Whether the potential KPD donor is willing to ship a kidney
- 166 • Whether the potential KPD donor is willing to donate a left kidney, right kidney, or
- 167 either kidney
- 168 • Whether the KPD candidate-donor pair and the transplant hospital are willing to
- 169 participate in a three-way exchange or a donor chain
- 170 • Whether the potential KPD donor and the transplant hospital are willing for the
- 171 potential KPD donor to be a bridge donor
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- 173 d. Donor HLA as defined in *Policy 13.5.C: HLA Typing Requirements for OPTN KPD Donors*
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- 175 5. The potential KPD donor must be paired to an active and eligible candidate registered in the
- 176 OPTN KPD program or be a non-directed donor
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- 178 6. The transplant hospital registering the potential KPD donor must submit a response for all
- 179 previous match offers for the potential KPD donor in the OPTN KPD program, including reason
- for refusing offers
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- 178 7. The potential KPD donor must not be in a pending exchange in the OPTN KPD program

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