

Notice of OPTN Data Collection Change

Update Data Collection to Align with U.S. Public Health Service Guideline, 2020

Sponsoring Committee:	Ad hoc Disease Transmission Advisory
Data Collection Affected:	<i>Deceased Donor Registration (DDR)</i> <i>DonorNet®</i>
Public Comment:	August 3, 2021 – September 30, 2021
Board Approved:	December 6, 2021
Effective Date:	Pending implementation and notice to OPTN members

Purpose of Change

Text fields in multiple places in UNetSM make it difficult and labor intensive to analyze trends with donors that meet the risk criteria identified in the 2020 U.S. Public Health Service (PHS) Guideline for acute human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV). Lack of specific risk criteria as discrete fields and the way in which criteria are reported/documented leads to inefficiency in donor evaluation and limits effective monitoring of the *Align OPTN Policy with U.S. Public Health Service Guideline, 2020* policy changes approved by the Board of Directors in December 2020.

Proposal History

The 2020 PHS Guideline updated donor risk criteria for acute HIV, HBV, and HCV disease transmission through solid organ transplantation among other changes. Work on aligning OPTN policies with the 2020 PHS Guideline highlighted the need for better data collection. The ad hoc Disease Transmission Advisory Committee (DTAC) consulted with the Data Advisory Committee (DAC) to ensure alignment with data collection principles. The proposal was widely supported during public comment and was approved as part of the consent agenda at the December 2021 Board meeting.

Summary of Changes

Fields will be added to the overall risk question in the UNetSM systems DonorNet[®] and the Transplant Information Electronic Data Interchange[®] (TIEDI) Deceased Donor Registration (DDR). Options for “yes” and “no,” will apply for all risk criteria; “not applicable” will be an option for the two pediatric risk criteria. Below are the specific risk criteria identified in the 2020 U.S. PHS Guideline for behavior of the donor in the past 30 days that will be added as fields in UNetSM:

1. Sex (i.e., any method of sexual contact, including vaginal, anal, and oral) with a person known or suspected to have HIV, HBV, or HCV infection
2. Man who has had sex with another man
3. Sex in exchange for money or drugs
4. Sex with a person who had sex in exchange for money or drugs
5. Drug injection for nonmedical reasons
6. Sex with a person who injected drugs for nonmedical reasons

7. Incarceration (confinement in jail, prison, or juvenile correction facility) for 72 or more consecutive hours
8. Child breastfed by a mother with HIV infection
9. Child born to a mother with HIV, HBV, or HCV infection
10. Unknown medical or social history

Implementation

Operations affecting Organ Procurement Organizations

OPOs will use discrete data fields to report specific risk criteria. OPOs already collect the information as part of the donor assessment.

Operations affecting the OPTN

This data change will require programming changes in UNetSM; specifically, DonorNet[®] and the TIEDI DDR form. DonorNet[®] alignment will include updating the mobile DonorNet[®] application to display the new fields. This data change requires the submission of official OPTN data that are not presently collected by the OPTN. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in §121.11 of the OPTN Final Rule will be collected through the Office of Management and Budget (OMB) approved data collection forms. Therefore, the forms will be submitted for OMB approval under the Paperwork Reduction Act of 1995. This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

Affected Data Collection

DonorNet[®] addition

ADD: individual risk criteria as fields to “overall risk” question

- Options for “yes” and “no,” for all risk criteria; “not applicable” for two pediatric risk criteria
- Fields use text of 10 risk criteria:
 1. Sex (i.e., any method of sexual contact, including vaginal, anal, and oral) with a person known or suspected to have HIV, HBV, or HCV infection
 2. Man who has had sex with another man
 3. Sex in exchange for money or drugs
 4. Sex with a person who had sex in exchange for money or drugs
 5. Drug injection for nonmedical reasons
 6. Sex with a person who injected drugs for nonmedical reasons
 7. Incarceration (confinement in jail, prison, or juvenile correction facility) for 72 or more consecutive hours
 8. Child breastfed by a mother with HIV infection
 9. Child born to a mother with HIV, HBV, or HCV infection
 10. Unknown medical or social history

DDR addition

ADD: individual risk criteria as fields to “overall risk” question

- Options for “yes” and “no” for all risk criteria; “not applicable” for two pediatric risk criteria
- Fields use text of 10 risk criteria (see list above)