

PHS Risk Criteria Data Collection

OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC)

Background

- In June 2020 U.S. Public Health Service (PHS) guideline published for assessing solid organ donors and monitoring transplant recipients for HIV, HBV, HCV infection
- OPTN Board approved the updated policy to align with the 2020 PHS guidelines
- During development of the new policy, lack of granular data regarding risk criteria for HIV, HBV and HCV was identified as a hurdle to understand the repercussions of the new policy

Purpose of Proposal

- Collect more granular HIV, HBV, HCV risk criteria data to better evaluate donor risk criteria trends that could impact patient safety and organ utilization
- Inform future iterations of PHS Guideline and assess the impact of OPTN policy changes
- Support more efficient donor evaluation with discrete data fields

Proposal

- Add individual PHS Risk Criteria as discrete fields to “overall risk” question in DonorNet[®] & TIEDI[®] Deceased Donor Registration (DDR) form
- Options for “yes,” “no,” and “unknown” for all risk criteria
- Options for “not applicable” for two pediatric risk criteria

Rationale

- Current data collection of PHS Risk Criteria in UNetSM is limited and difficult to analyze
 - Information about specific criteria entered in text fields, not discrete fields
 - Labor intense process to sample text fields, may require subjective interpretation, significant limitations to analyze data
- Collecting better data on specific risk criteria will
 - Help ensure patient safety by evaluating the connection between risk criterion and rate of transmission
 - Support effective review of OPTN policy implemented to align with 2020 PHS Guideline
 - Inform future iterations of the PHS Guideline

Member Actions

- No actions needed by histocompatibility laboratories or transplant hospitals
- OPOs would enter specific risk criteria into discrete fields in DonorNet[®] and the TIEDI[®] DDR instead of in text fields as done currently

Extra Slide

Current PHS 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