

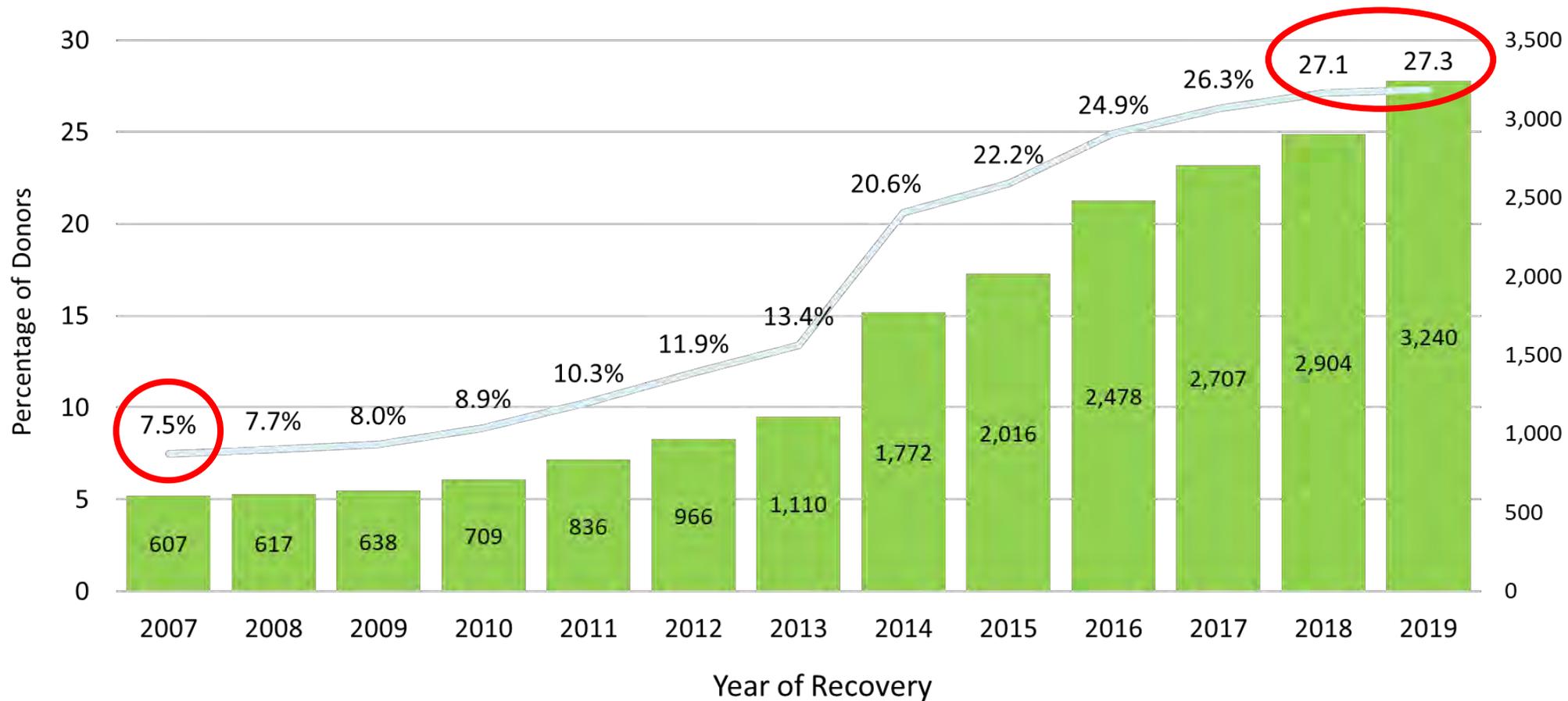
Align OPTN Policy with U.S. Public Health Service Guideline, 2020

Ad Hoc Disease Transmission Advisory Committee

Purpose of Proposal

- In June 2020, the U.S. Public Health Service (PHS) updated the Guideline for assessing solid organ donors and monitoring transplant recipients for human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) infection
- Final Rule requires that OPTN policies are consistent with the Guideline

PHS Increased Risk Donor: 2007-2019



Major Areas of Policy Change

- Risk assessment of living and deceased donors
- Living and deceased solid organ donor testing
- Transplant candidate informed consent
- Recipient testing and vaccination
- Collection and storage of donor and recipient specimens

Proposal

- Remove label “increased risk donor”
- Shorten timeframe for donor risk criteria assessment from 12 months to one month
- Remove hemodilution as infectious disease risk criteria in policy
- Require deceased donor testing specimens drawn within 96 hours of procurement
- Require living donor recovery hospitals to arrange storage of pre-transplant samples for 10 years
 - This matches current policy for deceased donor samples

Proposal

- Remove requirement for a separate informed consent when donors meet risk criteria
- Require assessment of need for HBV vaccination during candidate medical evaluation and report vaccination status
- Add required testing:
 - Candidate pre-transplant for HIV, HBV, and HCV during transplant hospital admission but before transplant occurs
 - Universal NAT for HIV, HBV, HCV on all transplant recipients 4-8 weeks after transplant
 - Liver recipient testing between 11-13 months post-transplant for HBV NAT

Member Actions

OPO

- Modify donor screening assessment for identifying donor risk criteria
- Obtain repeat tests if procurement does not occur within 96 hours when infectious disease samples first drawn

Transplant Hospital

- Complete additional required testing for living donors, candidates, and recipients
- Update candidate evaluations to include assessment for HBV vaccination need
- Report reasons HBV vaccination cannot be initiated or completed prior to transplant
- Arrange for living donor specimen storage

Feedback Requested

- 1) Data collection related to HBV immunity status may be expanded to include more specific information on HBV vaccination status and barriers to completion. Feedback is requested on the feasibility of and support for collecting additional data related to HBV vaccination status.
- 2) What is the appropriate length of time to require living donor specimens be stored by recovery hospitals? Why?
- 3) In order to evaluate the effectiveness of the revised *PHS Guideline*, reporting of additional specific risk criteria by OPOs would be needed. Feedback is sought on the feasibility of additional reporting of specific risk criteria.

Feedback Requested

- 4) Hemodilution was removed from the PHS risk criteria for 2020. Please comment on whether hemodilution should remain in policy.
- 5) Please comment on the post-transplant testing requirements in policy, as part of this proposal:
 - HIV, HBV, and HCV NAT at four to eight weeks post-transplant
 - HBV NAT at eleven to thirteen months post-transplant for liver recipients

Please introduce yourself when you speak

Align OPTN Policy with U.S. Public Health Service Guideline, 2020

- Aligns policy language to PHS Guideline, as required by the Final Rule
- Changes risk criteria to be less restrictive, however additional testing is added as a safety measure
- Changes prompted from community request; unexpected disease transmission of HIV, HBV, HCV is very low
- Goal is to increase number of transplants

Feedback is summarized and shared as public comment