

**OPTN Disease Transmission Advisory Committee (DTAC)  
Meeting Minutes  
April 1, 2019  
Conference Call**

**Marian Michaels, MD, MPH, Chair  
Ricardo La Hoz, MD, Vice Chair**

**Introduction**

The Disease Transmission Advisory Committee met via Citrix GoToTraining teleconference on 04/01/2019 to discuss the following agenda items:

The Committee met to develop recommendations on Increased Risk Designation (IRD). The Chair will present the OPTN recommendations to HHS on April 15, 2019.

1. Timeline for changes to IRD policy
2. Question 1: Is a new term needed to replace Public Health Service (PHS) IRD
3. Question 2: Should donors continue to be identified based on risk factors for HIV, HBV, HCV?
4. Question 3: Should time be shortened from 12 months?
5. Question 4: Are there specific criteria which should be eliminated or revised?

The following is a summary of the Committee's discussions.

**1. Timeline for changes to IRD policy**

This timeline shows which groups are involved in IRD policy development and when these groups will hear DTAC's recommendations.

Summary of discussion:

- April 1, 2019: DTAC creates recommendations.
- April 12, 2019: Recommendations to OPTN Executive Committee for approval.
- April 15-16, 2019: Chair presents OPTN recommendations to the United States Department of Health and Human Services (HHS).
- May 2019-December 2020: The Center for Disease Control and prevention (CDC) recommendations to public comment (upon approval by HHS).
- After December 2020: Final recommendations published.
- Post final CDC recommendations: OPTN changes policy to reflect final CDC recommendations.

Next Steps:

DTAC created recommendations on 4/1/19 and will continue to follow the presented timeline.

**2. Question 1: Is a new term needed to replace Public Health Service (PHS) IRD**

DTAC discussed options surrounding new terminology to replace "Increased Risk Donor".

Summary of discussion:

- Members agreed that a different term is needed to replace PHS Increased Risk Donor due to its negative connotation.
  - Cognitive bias could lead a potential recipient to reject an organ despite the probable positive outcomes of accepting the organ.
- Members thought about two ways to reframe the term:

- Option 1. Using the term “potential” risk donor instead of the term “increased” risk donor
- Option 2. Have 3 severities in order to classify IRD organs at a more realistic risk level:
  - PHS A: No further testing required based on PHS risk identification
  - PHS B: Further testing required based on identified potential risks
    - Behavioral risks or absence of adequate information
    - Equivalent to current PHS IRD
  - PHS C: Further testing/treatment based on positive donor test
    - Donor with positive HCV Nucleic Acid Test.
- A member inquired about recommending the establishment of a policy that would be prescriptive in stating why an IRD offered organ is considered a risk.
  - Another member reported that she had heard strong arguments on both sides of this issue across regions.
  - A member recommended that in the future, when this issue is reexamined, that it may be informative to gather the community’s sentiment.
- A member reported that he would recommend option 2 because it focused on testing rather than (the realistically very low) risk.
- DTAC recommendation: Option 2.

Next Steps:

DTAC will recommend option 2 to the OPTN Executive Committee for approval on April 12, 2019.

**3. Question 2: Should donors continue to be identified based on risk factors for HIV, HBV, HCV?**

DTAC discussed the importance of a classification system for HIV, HBV, and HCV.

Summary of discussion:

- Members discussed if there should be an IRD at all.
  - Members recommended not abolishing IRD:
    - If there was a transmission of HIV public trust and feelings of transparency could be lost.
    - IRD established rules on required testing and offer of treatment should a living donor have a positive test result.
- DTAC recommendation: Keep classification system for HIV, HBV, and HCV.

Next Steps:

DTAC will recommend keeping a classification system for HIV, HBV, and HCV to the OPTN Executive Committee for approval on April 12, 2019.

**4. Question 3: Should time be shortened from 12 months?**

DTAC discussed guidelines on the timeline for testing.

Summary of discussion:

- Members agreed that the guideline should be shortened from 12 months.

- NAT is the nearly universal test and has decreased the eclipse period, making 12 months too conservative.
- It was noted that CDC is not asking for a specific amount of months, but that DTAC can make a recommendation as specific as this if they would like to.
- Members considered 1 and 3 month guidelines:
  - DTAC sought consensus or great majority from the entire committee and have asked each member to email the chair with their vote.
  - So far it looks as though DTAC will recommend 1 month as a new guideline.

Next Steps:

DTAC will come to a consensus on the guideline and present this to the Executive Committee for approval on April 12, 2019.

**5. Question 4: Are there specific criteria which should be eliminated or revised?**

DTAC discussed if any of the 12 criteria for IRD should be removed or amended.

Summary of discussion:

- Members examined data: 2018: 2904 donors considered IRD. Sampled 10%, N = 290 (removal of 2 that were not actually IRD) N= 288.
  - Majority of donors had only 1 criteria for IRD. (179 donors or 62%)
  - Most common criteria were incarcerations (not sure exactly when incarceration occurred) and IVDA.
    - The adoption of a shorter guideline should have an impact on incarceration numbers.
  - Among the 479 pediatric donors 47 (10%) were PHS IRD. 60% of these patients' reason for PHS IRD classification was hemodilution- an extremely low risk for pediatric patients.
    - Members agreed that if HHS does not eliminate hemodilution, they should at least try to make an exception for pediatric patients as organs are likely being unnecessarily turned down due to their IRD classification.
  - Members all agreed that they wanted to eliminate hemodialysis from the criteria at a previous meeting (March, 18 2019).
  - STI:
    - Members believed that it would be difficult to separate the different STIs, but that the advised change to the time guideline will positively impact this criteria.
- DTAC Recommendations:
  - Removal of hemodialysis
  - Removal of hemodilution, with special attention paid to pediatrics and their low risk.
  - Non- removal of STIs and incarceration- a shorter timeframe guideline will positively impact these criteria.

Next steps:

DTAC will recommend eliminating hemodilution and hemodialysis from the IRD criteria to the OPTN Executive Committee for approval on April 12, 2019.

**Upcoming Meetings**

- April 12, 2019: Recommendations to OPTN Executive Committee for approval.
- April 15-16, 2019: Chair presents OPTN recommendations to HHS

- April 22 (Teleconference)
- May 20 (Teleconference)
- June 17 (Teleconference)