OPTN Ad Hoc Disease Transmission Advisory Committee
Meeting Summary
October 7, 2025
Conference Call

Stephanie Pouch, MD, MS, Chair
Rachel Miller, MD, Vice Chair

Introduction

The OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC or the Committee) met via Microsoft Teams on 10/07/2025 to discuss the following agenda items:

1. Welcome & Announcements
2. Discussion: Policy clarification – deceased donor exposure to HPDGH (OPTN Policy 2.4)
3. Discussion: Policy clarification – Chagas confirmatory testing pathways (OPTN Policy 2.9)
4. Public Comment Feedback and Policy Finalization: *Require Seasonal West Nile Virus Testing for All Donors*

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

1. Welcome and Announcements

The Chair welcomed the Committee.

2. Discussion: Policy clarification – deceased donor exposure to HPDGH (OPTN Policy 2.4)

Decision #1: The Committee agreed to pursue a policy clarification to exclude pediatric donors aged 12 and under from screening history regarding exposure to Human Pituitary Derived Growth Hormone (HPDGH) and will vote on policy language at a future date.

The Committee reviewed a presentation and received feedback from representatives from the American Association of Tissue Banks (AATB) regarding OPTN *Policy 2.4: Deceased Donor Medical and Behavioral History.*

Summary of presentation:

Current OPTN *Policy 2.4* requires OPOs to include whether a potential deceased donor has a history of prior exposure or treatment with non-recombinant Human Pituitary Derived Growth Hormone (HPDGH).

Background:

- From 1963 to 1985, nearly 7,700 children were treated with non-recombinant HPDGH for failure to grow
- In 1985, the US Department of Health and Human Services (HHS) stopped distribution of non-recombinant HPDGH following reports that three young adults who had been treated with HPDGH died of Creutzfeldt-Jakob (CJD) disease (a type of prion disease)
- HHS subsequently identified 36 cases of CJD among the ~7,700 treated

- None of the 36 people who got CJD began treatment with non-recombinant HPDGH after 1977, when a new purification step was added to the production process

AATB provided the OPTN with the following written feedback:

- *It has come to our attention that at least one OPO has been cited during a UNOS assessment for not collecting information regarding potential exposure of a pediatric donor to HPDGH.*
- ***The current position of AATB is that this requirement should not apply to pediatric donors, as the discontinuation of HPDGH use in the 1980s would have eliminated the risk for a pediatric donor population.***
- *This position appears to represent transplant industry consensus at least as of 2016, when a determination was made NOT TO include a related question as part of the pediatric (Child Donor ≤12 years old) Uniform Donor Risk Assessment Interview.*
- *Our understanding is that OPOs generally were not collecting this information prior to the recent assessment citation. If this requirement were to be enforced, all OPOs would need to implement collection of related information in their processes and information systems. We hope to avoid such widespread implementation if the requirement is indeed unnecessary.*
- Potential next steps
- Clarify in policy that pediatric donors are excluded from the requirement to consider if a potential deceased donor has a history of prior exposure or treatment with non-recombinant HPDGH

Summary of discussion:

Representatives from the AATB explained that their organization is the steward of the Universal Donor Risk Assessment Interviews (UDRAIs). There is a UDRAI identified for use in pediatric donors aged 12 and under, and another UDRAI for use in donors 13 and older. In 2016, a workgroup recommended removal of the question regarding HPDGH exposure on the pediatric UDRAI. The AATB's understanding is that there is no use of human pituitary derived growth hormone anywhere in the world.

The Chair agreed that a policy update is appropriate. The Ex Officio also supported updating the policy to exclude pediatric donors from the requirement for Organ Procurement Organizations (OPOs) to assess potential exposure to human pituitary-derived growth hormone (HPDGH). They noted that asking about this on the pediatric UDRAI could cause confusion. They also asked whether the adult UDRAI should be updated to exclude donors born after 1985.

An AATB representative commented that adding age-based questions to the adult DRAI could complicate the process. The pediatric UDRAI is used for donors aged 12 and under, and they recommended simply excluding donors 12 and under from the requirement in policy.

The Committee reviewed draft policy language to reflect this clarification.

Next steps:

The draft policy clarification will be distributed to the Committee for further review. The Committee will vote on a future meeting or via email to send the policy clarification forward to the OPTN Board of Directors.

3. Discussion: Policy clarification – Chagas confirmatory testing pathways (OPTN Policy 2.9)

Decision #2: The Committee agree to pursue a policy clarification regarding acceptable confirmatory testing for Chagas and will vote on policy language at a future date.

The Chair presented updates regarding Centers for Disease Control and Prevention (CDC) processes for Chagas testing and implications for recently implemented OPTN policy.

Summary of presentation:

The OPTN policy regarding Chagas testing that was implemented on 10/01/2025 requires OPOs to submit a sample for confirmatory testing within 72 hours of receipt of a positive Chagas antibody donor screening test.

- The policy states that confirmatory testing may be achieved by either submission through the CDC, or by performance of at least two different FDA licensed, approved, or cleared antibody diagnostic tests.
- There have been changes to CDC testing processes since the policy was approved by the OPTN Board of Directors. CDC no longer performs two confirmatory tests for Chagas as was the practice in 2023 when the policy was developed and approved.
- Leading up to implementation, members submitted feedback and questions regarding the new policy. Question themes included:
    - Confusion on use of CDC for confirmatory testing
    - Confusion regarding number of confirmatory tests required
- DTAC leadership consulted with CDC to develop the following FAQs on this issue which are awaiting final approval before sharing with members and posting to the OPTN website.
    - **Q: Can OPOs submit a sample to the CDC for confirmatory testing?**
    - Yes, per policy OPOs may submit a sample to the CDC for confirmatory testing. However, there have been changes to CDC processes since the time of policy finalization and it is recommended that OPOs utilize commercial laboratories instead of the CDC if the OPO is unable to perform two confirmatory tests. The OPTN is exploring how to best update or clarify policy to reflect current CDC processes. Members may contact member.questions@unos.org with additional questions.
    - **Q: Does CDC perform two confirmatory tests?**
    - There have been changes to CDC processes since the time of the policy finalization. Today the CDC testing involves only one confirmatory test, which is not sufficient to diagnose Chagas disease. While, per policy, OPOs may still submit a sample to the CDC, OPOs may find it more practical to utilize commercial laboratories which can perform two simultaneous confirmatory tests for Chagas.
    - If submitting a sample to the CDC, and a positive test result is returned, an additional confirmatory test is required to accurately confirm a Chagas diagnosis. The OPTN is exploring how to best update or clarify policy to reflect current CDC processes. Members may contact member.questions@unos.org with additional questions.

    - If a sample is sent to the CDC for confirmatory testing and the result is negative, no additional testing is needed to confirm the negative result.
- DTAC is now considering a policy clarification to remove the "submission through the CDC" language from policy and reduce further confusion among OPOs.
    - A potential update to policy would be to state the requirement as: "Confirmatory testing requires performance of at least two different FDA licensed, approved, or cleared antibody diagnostic tests."

Summary of discussion:

The Chair noted that if samples are sent to the CDC today for a confirmatory test, the CDC can only provide one confirmatory test, which if positive, is not sufficient to diagnose Chagas. They continued that it will be most efficient to facilitate testing through outside commercial laboratories that provide both tests.

A Committee member asked whether a list of acceptable Chagas tests and commercial laboratories could be provided to OPTN members to help them meet the new requirements. Another Committee member asked if outside commercial laboratories were offering two tests. The Chair noted that several commercial labs offer two tests, either as simultaneous tests or as reflex sequence. The Chair noted that the OPTN cannot provide specific laboratory information but can point to the FDA website for more information. The Vice Chair expressed support for the proposed approach to clarify the policy by removing the reference to submitting through the CDC and commented that the policy change appeared straightforward. Other Committee members also supported the change and agreed that removing the reference to the CDC would clarify the policy for OPTN members.

Next steps:

The draft policy clarification will be distributed to the Committee for further review. The Committee will vote on a future meeting or via email to send the policy clarification forward to the OPTN Board of Directors.

4. Public Comment Feedback and Policy Finalization: *Require Seasonal West Nile Virus Testing for All Donors*

Decision #3: The Committee agreed to review policy options concerning extension of the living donor testing timeline in the proposal.

Decision #4: The Committee agreed to provide more data and evidence to support other aspects of the proposal in the presentation to the Board of Directors.

The Committee reviewed the public comment feedback on the *Require Seasonal West Nile Virus Testing for All Donors* proposal.

Summary of presentation:

The proposal was released for public comment from August 27 – October 1, 2025, and received 219 comments through virtual regional meetings, committee meetings, and the OPTN website. The average sentiment score was 3.7 out of 5.

The following public comment themes were shared with the Committee:

- General support for the proposal and its patient safety goals
- Requests to modify the proposed 7-day testing timeline for living donors
    - Proposed policy language requires all living donors to be tested within 7 days prior to organ recovery
        - Most commenters on this topic requested modifications to the 7-day timeline
        - Commenters noted:
            - The 7-day requirement would be impractical and cause excess burden on transplant programs and living donors, potentially delaying surgeries
            - The 7-day requirement would not align with current living donor testing practices and requested that programs be allowed to perform West Nile Virus (WNV) testing at the same time as other required tests
        - Many commenters recommended a 28-day window, while others proposed 10 to 14 days
- Concerns about testing turn-around times for deceased donor testing and potential organ loss
    - Proposed policy language requires NAT results for WNV be available prior to implantation.
        - Some commenters expressed concern about this requirement, describing logistical challenges and the potential for organ loss due to delayed WNV results
        - Other commenters noted their experience in obtaining WNV NAT results with a short turn around time
        - Some commenters suggested the Committee consider exceptions or permit flexibility to allow transplant to proceed in certain cases if WNV NAT results are not available. Scenarios cited by commenters included rush DCD cases, urgent recipient cases, and low risk donors.
- Concerns regarding the accuracy of testing results and utility tradeoffs of the proposal
    - Commenters expressed concern about the accuracy of WNV NAT and the overall utility of the proposal in light of the data provided on WNV transmissions
        - Some commenters questioned specifically the effectiveness of the WNV NAT when used on blood samples
        - Other comments included opposition to the proposed testing requirements, citing concerns that false positives would result in greater organ loss than patient benefit given the rate of WNV transmissions
        - Several comments also requested the Committee provide more data to evaluate the utility and tradeoffs of the proposal. Comments included requests for data prior to the proposal's adoption and data as part of the proposal monitoring plan
- Seasonal and geographic considerations
    - Some commenters asked the Committee to consider limiting testing requirements to geographic areas where high WNV activity is observed
    - Other comments suggested modification of the proposed seasonal window for required testing

<u>Summary of discussion:</u>

A member suggested extending the turnaround time for living donor testing to 14 days to support transplant programs that rely on larger reference labs. Alternatively, they proposed that transplant

hospitals coordinate with their Organ Procurement Organizations (OPOs), which can often return results more quickly for deceased donors.

The Ex Officio acknowledged concerns about coordinating care and timelines for living donors but expressed concerns around extending the timeline. They emphasized that West Nile Virus (WNV) positivity is an acute condition, and the current 7-day window is the most appropriate from an epidemiological standpoint to prevent transmission.

Another member noted that data on transmission rates from deceased versus living donors is lacking. Public comments from hospitals working with living donors indicated they do not view WNV transmission as a major concern. Instead, they see the 7-day testing requirement as a logistical burden, especially when needing to bring donors back pre-transplant.

A member shared that transplant programs often bring in living donors within four days of the transplant to complete testing. They noted the challenge seems to be less about getting test results within seven days and more about having to adjust existing workflows.

The Chair noted similar feedback and raised a question about how to manage testing for domino transplants, where timing can be especially challenging. A member agreed that testing within 7 days is ideal but suggested the group may need to consider a longer window to ensure testing is feasible for all transplant programs. The Ex Officio noted that if the Committee decides to extend the testing window, it is important to provide educational materials explaining that the further testing occurs from the time of donation, the more risk and uncertainty it introduces.

The Chair noted that if the timeline is extended, it would be a useful opportunity for transplant programs to talk with potential living donors about ways to reduce the risk of disease between testing and donation.

The Ex Officio asked whether members would like to discuss additional components of the proposal.

One member recommended including more information about the test's accuracy and the low likelihood of false positives. They noted that some comments suggested limiting testing to certain geographic areas or adjusting the timing of the test. However, the member emphasized that the data support the proposal's seasonal testing window. While some regions have higher transmission rates, the disease is present nationwide. Additionally, donor travel history may not be known at the time of donation.

The Chair agreed and suggested adding visual references from ArboNet or the CDC to show that WNV is found across the U.S. and that its impact varies year to year. They also noted that last year's burden was significant.

A member recommended clarifying that diagnosis typically occurs when symptoms are present, but 80% of WNV infections are asymptomatic. Most cases are mild and go unnoticed, which may contribute to the perception that testing is unnecessary.

The Chair added that public comments included questions about whether certain organ types are more affected. They recommended clarifying that no specific organ type is more likely to transmit WNV and emphasized that there is no treatment or preventive measure available once transmission occurs.

<u>Next steps:</u>

The Committee will review policy options and vote to finalize changes in a future meeting or via email.

Upcoming Meeting

- October 27th, 2025 (closed)

Attendance

- **Committee Members**
  - Stephanie Pouch, Chair
  - Lara Danziger-Isakov, Ex Officio
  - Gerald Berry
  - Riki Graves
  - Jaskiran Kaur
  - Dong Heun Lee
  - Gabriel Maine
  - Tanvi Sharma
  - Fernanda Pinho Silveira
- **HRSA Staff**
  - Raymond Lynch
- **UNOS Staff**
  - Lindsay Larkin
  - Rebecca Murdock
  - Kaitlin Swanner
  - Susan Tlusty
- **Other Attendees**
  - Mario Sindaco
  - Melissa Greenwald