OPTN Ad Hoc Disease Transmission Advisory Committee
Meeting Summary
September 2, 2025
Conference Call

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

Introduction

The OPTN Ad Hoc Disease Transmission Advisory Committee (the Committee) met via WebEx on 09/02/2025 to discuss the following agenda items:

1. Welcome and Announcements
2. Review & Discussion: Cross-Committee Feedback to Rabies Proposal
3. Review & Discussion: Updated Rabies Proposed Policy Language and Data Collection
4. Adjourn

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

1. Welcome and Announcements

The Chair welcomed the Committee. The Chair thanked Committee members for presenting the Committee's proposal: "Require Seasonal West Nile Virus Testing for All Donors" at upcoming Regional Meetings. The Chair provided notice that Committee Members will be assigned larger than normal batches of case reviews for the months of September and October. The Chair reviewed the goals for the meeting: review prior discussions on the Rabies directive, review cross-committee and Centers for Disease Control (CDC) feedback, receive input from visiting stakeholder Committee members, and discuss revisions to the draft data collection and policy language.

2. Review & Discussion: Cross-Committee Feedback to Rabies Proposal

Decision #1: No decisions were made

The Committee reviewed an overview of the HRSA Rabies Directive and the Committee's progress to date.

Summary of presentation:

In 2024, a donor derived rabies transmission occurred.

- In April 2025, HRSA directed the OPTN Disease Transmission Advisory Committee (DTAC) to propose improvements to OPTN policy that reduce the risk of donor-derived rabies.
- The directive includes the following:
    - Gathering data from six Organ Procurement Organizations (OPOs) to help inform these policy improvements

- Propose policy improvements to OPTN policy that reduce the risk of donor-derived rabies
- Draft data collection via a minimal, non-burdensome additional data field in the Deceased Donor Registration form
- Collaborate with the OPTN Patient Affairs Committee (PAC), Transplant Coordinators Committee (TCC), and OPO Committee on how to integrate patient and provider perspectives, concerns, and education into any proposed policy changes as well as any potential recommendation for the use of post-exposure prophylaxis

- On July 11th, representatives from the CDC presented its analysis of the OPO data and recommendations to DTAC Leadership
- On the August 1st DTAC Leadership Call, HRSA requested the DTAC proceed with the policy development and data collection portion of the directive
- On August 12th, representatives from CDC presented their analysis to the full DTAC, and the Committee reviewed and discussed draft data collection and policy
- From August 12th – today's meeting, multiple engagements with other OPTN Committees and the CDC have occurred:
  - Briefings to the OPO Committee, TCC Committee, Living Donor Committee Leadership, Patient Affairs Committee Leadership, Data Advisory Committee (DAC) Leadership
  - Additional CDC feedback was received on August 29th.
  - Representatives from PAC, OPO, TCC, Living Donor, and DAC have been invited to today's meeting to provide additional input
  - DTAC will brief the full DAC on the proposal on September 8th
- Today provides an opportunity to review the feedback DTAC has received so far and determine policy issues

The Committee reviewed the draft policy and data collection proposal that was discussed at DTAC's August 12th meeting, and the cross-committee feedback that was received.

- Following the August 12th DTAC Meeting, the Committee suggested the following screening criteria to help stratify the risk of rabies exposure in a potential organ donor:
  - Occupational contact with high-risk wildlife (veterinarians, veterinary technicians, animal control officers, and wildlife workers)
  - Direct contact with bats within the last 12 months
  - Bite or scratch within the last 12 months from a wild mammal in the United States (bats, raccoons, skunks, foxes, mongoose, or other if endemic to area)
  - Unprovoked bite or scratch from any domestic mammal within the last 12 months
  - Bite or scratch within the last 12 months from any wild or domestic mammal outside of the United States (includes dogs, cats, and other domestic or wild mammals)
  - Unknown due to missing or incomplete medical/social history

- The Committee also agreed on draft policy that would:
  - Require OPOs to consult with the CDC or state/local health departments if a potential donor meets any of the established criteria that would put organ recipients at risk of acquiring rabies, and communicate that evaluation to the transplant program. (OPTN Policy 2.4)
  - Require transplant programs to: (OPTN Policy 15.3.B):

        - Inform intended recipients that risk criteria are present
        - Discuss results of risk assessment or evaluation obtained by OPO from state/local health department or CDC
        - Discuss options to mitigate risk through early administration of PEP
    - Add high risk rabies exposure screening criteria to medical evaluation requirements for Living Donors (OPTN Policy 14.4)
- This proposal was shared with other OPTN committees and the CDC for feedback
    - On August 21st DTAC Leadership presented to the Organ Procurement Organization (OPO) Committee
        - OPO Committee Members expressed that the proposed risk screening questions are generally reasonable for OPOs to answer, but raised concern regarding terms like occupational risk and "unprovoked" domestic animal encounters. They noted these terms may be overly broad or ambiguous.
        - An OPO Committee Member requested to clarify that OPOs would not be making decisions to rule out a donor for transplant based on a screening criteria. Rather OPOs are responsible for providing information to the transplant program.
        - OPO Committee Members requested more guidance on how a quantitative tool described by the CDC could be accessed and how OPOs may use this tool. Members noted that if a tool were incorporated into the OPTN system, risk assessment on a donor could be automatically performed.
        - Members suggested DTAC coordinate where possible with the Food and Drug Administration and American Association of Tissue Banks to align with any updates to the Universal Donor Risk Assessment Interview.
    - On August 21st, a Committee Liaison presented to the Transplant Coordinators Committee (TCC)
        - TCC Members suggested revisions to proposed requirements for transplant programs. They suggested adding informed consent requirements and advised against requiring post exposure prophylaxis (PEP) in policy, highlighting the challenge in monitoring requirements relating to discussion topics
        - TCC Members requested more guidance for programs on the use of PEP and risk of PEP in transplant recipients, and how programs should monitor patients who accept organs with risk factors for rabies
        - TCC Members questioned how performance metrics might be impacted by the new policy proposal
        - A TCC Member also expressed concern around the process of expedited policy development and potential for unintended consequences
    - DTAC Leadership presented to the Patient Affairs Committee (PAC) Leadership on August 29th

- PAC Leadership provided feedback on strategies for providing educational resources for patients on the risks of accepting an organ with risk factors for rabies and what patients should know about receiving PEP
- PAC Leadership emphasized the need for information regarding clinical monitoring for recipients who accept certain organs and receive PEP and that patients must understand impacts of receiving PEP on their overall transplant recovery journey

- DTAC Leadership presented to the Living Donor (LD) Committee Leadership on August 29th
  - LD Leadership communicated that it is reasonable to include Rabies screening criteria in the medical questionnaire for Living Donors, and that this would also require data collection changes to the Living Donor Registration form
  - LD Leadership discussed the need for guidance and considerations for potential living donors and potential living donor recipients if rabies risk criteria are identified. For example, programs may need to understand if there is a recommended waiting period after receiving Rabies PEP for living donation?
  - LD Leadership greed to seek additional feedback from the Living Donor Committee Members.
- A Committee Liaison updated the Data Advisory Committee Leadership on August 18th, and DAC Leadership invited DTAC Leadership to brief the full DAC on their upcoming September 8th meeting
- The CDC provided additional feedback to DTAC Leadership on suggested screening criteria for Rabies on August 29th
  - The CDC recommended inclusion of hunters explicitly in an occupational risk question, suggesting language similar to "Occupational or frequent recreational contact…" and provided other wording adjustments to improve clarity of the criteria
  - The CDC supported the inclusion of "unprovoked" domestic animal bites or scratches and supported the addition of an "unknown" response option for OPOs when a donor's social history is missing
  - The CDC clarified that the quantitative tool described in previous presentations should not be used by OPOs in place of a consultation with the CDC or local health departments
  - The CDC recommended that as no formal guidance on administration of PEP to transplant recipients currently exists, clinicians and public health teams contact the Rabies team at CDC for individualized guidance

3. Review & Discussion: Updated Rabies Proposed Policy Language and Data Collection

Decision #1: The Committee agreed to adopt CDC's recommended screening criteria. Criteria will include occupational or frequent recreational contact with wildlife, including hunting. Criteria will also include unprovoked bites or scratches from animals in the United States.

Decision #2: The Committee agreed to require programs to obtain informed consent from patients when accepting an organ from a donor that has met a rabies screening criterion.

Decision #3: The Committee agreed monitoring requirements for transplant programs should align with standard clinical monitoring that is provided to recipients of rabies PEP.

Decision #4: The Committee agreed to apply the same policy requirements to living donors as those proposed for deceased donors.

The Committee reviewed a mockup of proposed data collection in the OPTN computer system and discussed updates to the Rabies screening criteria based on feedback from the CDC and OPTN Committees. The Committee considered if including criteria based on occupational or recreational risk and unprovoked domestic animal exposures would make the screening process too broad, or if these criteria are necessary to identify high-risk rabies exposures in potential donors.

Summary of discussion:

The Vice Chair asked whether individuals identified through the occupational risk screening question would typically be vaccinated for rabies, and how that might affect their overall risk.

- A CDC representative clarified that none of the screening criteria would automatically disqualify a donor. Instead, the information should be collected and reviewed in consultation with the CDC or other health authority to determine whether rabies PEP is needed for the recipient.
- The Chair asked whether vaccination status would be considered in those consultations. The CDC representative responded that it likely would, but such cases would require a more detailed discussion.

The Committee discussed whether the consultation requirement should include a reference to an infectious disease (ID) clinician. The Chair noted that ID consultation practices vary widely across OPOs and that referring OPOs to state health departments or the CDC may be clearer guidance.

The Vice Chair emphasized the importance of ensuring OPOs have a clear way to contact health departments or the CDC, including outside of business hours and on holidays.

- A CDC representative noted their intent to provide a contact list with phone numbers to support OPOs in reaching out as needed.

The Committee agreed to adopt the CDC recommendations for donor screening criteria relating to occupational and recreational risk and unprovoked bites or scratches from domestic mammals.

The Committee reviewed updated policy language reflecting feedback from cross-committee discussions.

- Members considered existing policies related to donor risk identified before transplant and discussed whether informed consent should be required when a recipient accepts an organ from a donor with rabies risk criteria, or if the documentation process used when Public Health Service (PHS) risk factors would be sufficient.

- A CDC representative noted that a separate informed consent process may not be necessary, as long as the conversation is documented.
- A representative from the PAC emphasized that recipients often do not recall discussions held immediately after transplant due to the overwhelming nature of the experience. It is important that caregivers are also informed. Another PAC member suggested providing information at multiple points after transplant.
- PAC representatives strongly supported the principle of informed consent and stressed that it should be communicated more than once, as patients must understand multiple risks.
- The Vice Chair asked whether informed consent should be documented in a specific form or if a note in the medical record would be sufficient, acknowledging that "informed consent" can mean different things in different settings.
- A PAC representative noted that if the risk to patients is significant enough to require a specific policy change, then a signed document and repeated communication post-transplant may be warranted.

- The Committee discussed proposed monitoring requirements for transplant programs when recipients accept an organ offer from a donor who meets a screening criterion for rabies. The Committee discussed whether requirements could incorporate the principle of multiple post-transplant communications. The Chair noted that monitoring requirements should not be specific to monitoring for disease development, as rabies testing is complex and typically only performed when clinically indicated. The Chair noted that rabies testing requires multiple samples and specialized testing at a CDC laboratory, and routine lab-based testing for active infection is not available.
  - A CDC representative recommended programs consider a 45-day follow-up period for recipients, which aligns with standard monitoring for individuals who receive rabies PEP. The CDC representative noted programs should also test recipients for rabies antibodies after receiving PEP.
  - The Chair agreed that the policy should refer to clinical monitoring requirements and standard practices used for individuals receiving PEP.
  - The Vice Chair raised concerns about the cost of PEP and how it would be reimbursed, noting that both the TCC and the PAC had expressed similar concerns. The Chair acknowledged the issue and suggested it may need to be addressed during the public comment period.
- The Committee discussed whether the proposal's requirements should also be applied to living donors. A CDC representative supported applying the same policy to both donor types.
  - The Chair noted that treatment may differ for living donors, as both the donor and recipient could require rabies prophylaxis. The CDC representative added that guidance from the CDC or state health department would help determine whether the living donor should receive PEP, and whether the recipient would also need it. For example, if the donor has completed their PEP course, the recipient may not require additional treatment. These decisions would be made on a case-by-case basis.
  - The Committee reached consensus to apply the same policy requirements to living donors as deceased donors.

4. Adjournment

Decision #5: No decisions were made.

The Chair thanked the Committee Members, federal partners, and visiting OPTN committee members for their participation and work on the proposal development.

Next steps:

Committee leadership will review feedback from this meeting and provide a briefing to the Data Advisory Committee (DAC) on September 8. The DTAC will reconvene in open session on September 22 to review the final policy language and vote on whether to advance the proposal for public comment. If approved, the proposal may be considered by the OPTN Board in October for a special public comment period.

Upcoming Meetings

- August 25, 2025 (closed session)
- September 2, 2025

Attendance

- **Committee Members**
  - Anna Hughart-Smith
  - Cindy Fisher
  - Fernanda Silveira
  - Gabriel Maine
  - Gerald Berry
  - Lara Danziger-Isakov
  - Rachel Miller
  - Stephanie Pouch
  - Cynthia Fisher
  - Shirish Huprikar
  - Tanvi Sharma
- **CDC Representatives**
  - Ian Kracalik
  - Sridhar Basavaraju
  - Kelsey McDavid
  - Pallavi Annambhotla
- **Other attendees**
  - Lorrinda Gray-Davis (PAC)
  - Molly McCarthy (PAC)
- **UNOS Staff**
  - Betsy Gans
  - Carly Rhyne
  - Lindsay Larkin
  - Kevin Daub
  - Cole Fox
  - Dzhuliyana Handarova
  - Logan Saxer
  - Sandy Bartal
  - Tory Boffo