OPTN Ad Hoc Disease Transmission Advisory Committee
Meeting Summary
August 12, 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 08/12/2025 to discuss the following agenda items:

1. Welcome and Announcements
2. Rabies Directive Update
3. CDC analysis and recommendations
4. Policy and data collection changes related to Rabies directive

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

1. Welcome and Announcements

The Chair welcomed the Committee. The Committee's *Clarify Disease Reporting Requirements* project was implemented on August 1st. The Chair announced the upcoming public comment period and reminded Members about upcoming regional meeting dates.

2. Rabies Directive Update

Decision #1: No decisions were made

The Committee reviewed an overview of the HRSA Rabies Directive and expectations for the meeting.

Summary of presentation:

In 2024, a donor derived rabies transmission occurred.

- In April 2025, HRSA directed the 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 Coordinator Committee (TCC), and Organ Procurement Organization (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 Centers for Disease Control (CDC) presented its analysis of the OPO data and recommendations to DTAC Leadership
- On August 1st DTAC Leadership Call, HRSA requested the DTAC proceed with the policy development and data collection portion of the directive
- Project will move on an expedited timeline with a goal to produce a proposal for public comment in 2025

The goals for the present meeting are to review the directive and CDC recommendations, consider potential changes to data collection fields, consider draft OPTN policy improvements, and provide feedback.

3. CDC analysis and recommendations

Decision #1: No decisions were made

Representatives from the CDC presented their analysis of data collected from OPOs. Their presentation included historical information on transplant-transmitted rabies in the United States and provided more detail regarding the index case. The presentation discussed the CDC's analysis of animal exposures among deceased organ donors and simulation to estimate exposure in the broader deceased organ donor population. The presentation introduced a quantitative assessment tool used to assess need for post-exposure prophylaxis following a potential rabies exposure. The presentation concluded with the following considerations for the Committee:

- **Rabies should be an absolute contraindication for organ donation**
    - **Need a standardized approach to the assessment of rabies risk among organ donors**
    - Uniform questions should be administered to next-of-kin to elicit the type of animal, timing of the exposure, and nature of the exposure
    - Establish criteria for high-risk rabies exposures
- **Establish guidance for OPOs and transplant centers when high-risk rabies exposures are identified in a potential organ donor**
    - The need for additional consultation and evaluation prior to organ procurement
    - Assessment of the need for rabies post-exposure prophylaxis in recipients of organs from donors with a documented high-risk exposure

Summary of discussion:

A Member asked if the mammal exposure in the index recipient was known at the time of donation. A CDC representative clarified that while the exposure was known, the details of the exposure were not fully understood until after the transmission event.

4. Policy and data collection changes related to Rabies directive

Decision #1: The Committee recommended not including definitions for "high risk" or "low risk" in the proposal

Decision #2: The Committee agreed that if any risk factor is answered "yes," the policy should clearly instruct the OPO to consult with the local health department or CDC.

Decision #3: The Committee agreed to seek additional feedback on the proposed policy and data collection questions from the OPO Committee and other OPTN stakeholder Committees.

The Committee considered draft data collection changes to assess donors for rabies risk factors. The Committee reviewed current questions relating to mammal exposure on the Uniform Donor Risk Assessment Interview (UDRAI) Form, and questions in the OPTN Computer System that could serve as data collection models. The Committee reviewed the list below of potential rabies risk factors, and considered what actions would be required by policy when a risk factor is present.

- Direct contact with bats within last 12 months
- Bite/scratch within last 12 months from a wild mammal in the United States (bats, raccoons, skunks, foxes, mongoose, or other if endemic to area)
- Bite/scratch from any wild or domestic mammal within the last 12 months exhibiting behavioral changes (aggression, unprovoked attacks, other signs of apparent illness)
- Bite/scratch within last 12 months from any wild or domestic mammal outside of the United States (includes dogs, cats, and other domestic mammals)
- ***Related policy question: If any of above are yes, how should OPO consider rabies risk evaluation with state/local health department and transplant program?***
    - Low risk/transplantation not contraindicated (discuss post-exposure prophylaxis [PEP])
    - High risk/Transplantation contraindicated – preclude matches/offers?

Summary of discussion:

The Chair discussed the benefits of structuring questions with individual fields, like the structure of the Public Health Service (PHS) questions, as this allows for easier querying of responses. Currently, such information is only accessible via the UDRAI) in PDF format. The Chair invited Committee members to provide feedback on the proposed list of questions.

A representative from the CDC noted that the question regarding behavioral changes may be subjective and challenging for OPOs to assess accurately. The Vice Chair noted that all questions in the proposed list would require more detailed history-taking from the next of kin, along with additional contextual information.

The Chair asked Committee members to identify any criteria from the list of questions that might be considered "high risk," and how OPOs and programs should consider those cases. A CDC representative shared that their modeling anticipates a small number of cases annually. A "yes" response to any question should not be viewed as a contraindication to transplant, but rather as a prompt for consultation with the health department or CDC to assess exposure risk and ensure appropriate PEP is provided to recipients.

The Chair noted that not all OPOs have access to an infectious disease consulting team at a transplant program. As a result, follow-up actions may need to be coordinated through a state or local health department or the CDC.

A Committee Member suggested that criteria such as whether the donor showed neurological symptoms or had an occupational exposure risk (e.g., working in wildlife rescue or animal shelters) should be considered. The Chair agreed these criteria may be captured under questions related to bites or scratches, but should be reviewed further.

The Vice Chair asked whether it would be possible to categorize questions by risk level (low vs. high) and emphasized the need for clear guidance. The Chair supported a simplified approach: if any question is answered "yes," it should prompt consultation with the health department or CDC. Based on that consultation, a decision can be made about whether PEP is needed for recipients.

A CDC representative noted that the risk calculator tool presented during the meeting is a useful way to assess whether PEP is needed.[1] The Chair agreed and suggested that directly referencing this tool during decision-making would be beneficial. The calculator can be interpreted to recommend PEP for recipients when the estimated risk exceeds 0.0004.

The Committee discussed how to document information from consultations with the CDC or health departments. The Chair recommended that, at a minimum, any insights from the risk calculator or consultation should be included in the donor highlights. A CDC representative added that tracking whether recipients receive PEP could be valuable, but deferred to the Committee. The Chair encouraged continued exploration of how to communicate the need for PEP through data collection or other parts of the process.

A Committee Member asked whether rabies has endemic areas where location-specific data could be useful. The CDC representative responded that this is not necessary for rabies. Any wild mammal in the United States is considered high risk, and any exposure outside the U.S., whether from wild or domestic animals, is also considered high risk.

The Committee then reviewed draft policy changes to reduce the risk of donor derived rabies and discussed considerations around the draft policy language.

- *2.4 Deceased Donor Medical and Behavioral History*
    - New language to require the OPO to contact the state or local health department or the CDC for additional evaluation prior to organ procurement
- *2.11 Required Deceased Donor Information*
    - Requiring OPOs to report to the OPTN criteria that would put organ recipients at risk for acquiring rabies
- *15.3.B Donors with Risk Identified Pre-Transplant*
    - Language requiring transplant programs to inform the potential transplant recipient about rabies risk criteria present in the donor and discuss options for early administration of PEP
- *14.4 Medical Evaluation Requirements for Living Donors*

[1]Risk assessment tool accessible at: https://kellycharniga.shinyapps.io/RabiesRiskTool/?_ga=2.192835374.528424846.1680190191-1149591592.1678282481

    - Language adding rabies risk exposures to the list of social history screening requirements for living donors

- *14.4.E Living Donor Exclusion Criteria*
    - Adding rabies diagnosis or high-risk rabies exposures to the list of living donor exclusion criteria.

The Chair recommended refining the wording of the data collection questions to help distinguish between provoked and unprovoked incidents, as this detail would be needed to utilize the quantitative assessment tool. No further discussion took place regarding the substance of the proposed policy changes. Committee Members agreed that consultation with the OPO Committee and additional OPTN stakeholder Committees will be important moving forward.

Next steps:

Committee leadership will review the feedback from today's meeting and seek additional input from the CDC as well as the OPTN PAC, TCC, OPO, Data Advisory Committee and Living Donor Committees. Work will continue to refine the wording of the data collection question. The DTAC will reconvene at its next open meeting on September 2nd to discuss any updates to the draft language.

The Committee also reviewed a draft timeline for the project. The full Committee may vote on the updated language as early as the next open session on September 2nd. Cross-Committee feedback will continue, with the goal of releasing the proposal for a special public comment period in 2025.

Upcoming Meetings

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

Attendance

- **Committee Members**
  - Gabriel Maine
  - Lara Danziger-Isakov
  - Rachel Miller
  - Stephanie Pouch
  - Cynthia Fisher
  - Jas Kaur
  - Shirish Huprikar
- **CDC Representatives**
  - Sridhar Bassavaraju
  - Kelsey McDavid
  - Pallavi Annambhotla
- **FDA Representatives**
  - Hanh Khuu
  - Irma Sison
- **UNOS Staff**
  - Carly Rhyne
  - Lindsay Larkin
  - Cole Fox
  - Dzhuliyana Handarova
  - Logan Saxer
  - Sandy Bartal
  - Sara Langham
  - Tory Boffo