OPTN Directive to Reduce the Risk of Donor Derived Rabies Transmission

OPTN Ad Hoc Disease Transmission Advisory Committee

Purpose of Proposal

- In April 2025, the OPTN received a directive to further reduce the risk of donor-derived rabies transmission
  - The Disease Transmission Advisory Committee was tasked with recommending updates to OPTN Policy
- The proposal seeks to improve patient safety by reducing the risk of rabies transmission via solid organ transplantation

Proposal

- Establish screening criteria for high-risk rabies exposures in deceased and living donor populations, and standardize data collection of the criteria
- Within the last 12 months did the donor have *any* of the following:
  - Direct contact with bats
  - Bite or scratch from a wild mammal in the United States (including but not limited to bats, raccoons, skunks, mongoose, or foxes)
  - Bite or scratch from any stray or feral cat
  - Bite or scratch from any wild or domesticated mammal (including dogs, cats, or other domesticated mammals) outside of the United States

Proposal

- Require OPOs and living donor transplant programs to contact the Centers for Disease Control and Prevention (CDC) for additional risk assessment and evaluation when screening criteria are identified in a donor
- Require transplant programs to inform potential recipients when screening criteria are identified, and provide appropriate clinical monitoring after transplant, including monitoring specific to the receipt of rabies post-exposure prophylaxis (PEP)

Rationale

- Rabies is a rare but severe disease in humans affecting the central nervous system
  - There is no effective treatment or cure for rabies once symptoms begin
  - Transmission most frequently occurs through the bite or scratch of an infected mammal but has also occurred through blood transfusion and solid organ transplant
  - No testing exists to diagnose rabies in humans prior to the onset of symptoms and clinical disease
  - Once a human has been exposed to rabies, prompt medical evaluation and the administration of PEP is critical to prevent disease development

Rationale

- From 2015 to 2024, there have been 17 cases of human rabies confirmed in the United States
  - While confirmed transmission of rabies to humans is rare, potential human exposure to rabies is broader
- There have been four instances of documented transplant-transmitted rabies involving deceased donors in the United States since 1979, resulting in seven recipient deaths
  - Post-mortem investigations of these transmissions sometimes revealed evidence of animal exposures and clinical symptoms associated with the rabies virus
  - Improved donor screening and consideration of PEP in transplant recipients may prevent future instances of transplant transmitted rabies

Rationale

Incidents of Donor-Derived Rabies Transmission

Event year	Recipient(s) outcome	Likely source of donor exposure
1979	• Corneal graft recipient: *Died*	Unknown animal exposure
2003	• Liver recipient: *Died* • Right kidney recipient: *Died* • Left kidney recipient: *Died* • Arterial graft: *Died*	Bat
2013	• Left kidney recipient: *Died* • Right kidney recipient: *PEP, survived* • Liver recipient: *PEP, survived* • Heart recipient: *PEP, survived*	Raccoon
2024	• Left kidney recipient: *Died* • Corneal graft recipient 1: *PEP, explantation, survived* • Corneal graft recipient 2: *PEP, explantation, survived* • Corneal graft recipient 3: *PEP, explantation, survived*	Skunk

Member Actions

- OPOs and living donor recovery hospitals will be required to be familiar with the screening criteria and comply with the updated reporting requirements
- If any criteria are met, OPOs and living donor transplant programs will be required to contact the CDC for additional evaluation prior to procurement or recovery and communicate that information to transplant programs
- Transplant programs will be required to provide information to recipients when risk criteria are present in a donor and comply with documentation and monitoring requirements

What do you think?

- Are the proposed rabies screening criteria clear and understandable to the community?
- Are there different or additional strategies to prevent rabies transmission in solid organ transplant that should be considered?
- Does the community support extending rabies screening requirements to living donors?
  - Are there different considerations for screening living donors for rabies risk that the Committee should contemplate?
- Are the proposed requirements for programs to inform patients when screening criteria are identified in a donor sufficient, or should more explicit informed consent requirements be adopted?
  - What educational resources would be beneficial for potential recipients who may accept an offer from a donor meeting rabies screening criteria?
  - How can information around the implications, benefits, and risks of receiving PEP best be provided to potential recipients in a transplant setting?

What do you think?

- What additional information would help OPOs and living donor programs operationalize the requirement to contact the CDC when a donor meets one of the rabies screening criteria?
- What experiences have OPO and living donor programs had with evaluating donors with reported animal exposures in their medical and social history?
  - Does your experience match the Committee's assumptions that donors meeting the proposed screening requirements will be low?
- How would OPOs and programs consider operationalizing the new requirements if the OPTN pursues a phased implementation approach?
  - Under this scenario, the policy requirements would take affect prior to rabies screening data collection being standardized in the OPTN Computer System, and OPOs would be required to consult the CDC if they observed any of the screening criteria in the donor history.