

**INTERIM REPORT OF THE  
OPTN/UNOS AD HOC DISEASE TRANSMISSION ADVISORY COMMITTEE**

**September 1, 2010  
Chicago, Illinois**

The OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee met in Chicago, Illinois on September 1, 2010, and considered the following items:

1. Dr. Emily Blumberg, Chair, welcomed new and returning committee members and asked all members introduced themselves and provide background for their roles on the committee.
2. The Committee reviewed its 2010-2011 goals, and what had been done to meet these goals to date:
  - Recommend modifications to OPTN policies 2.0 and 4.0 to improve screening and diagnostic testing for donor disease transmission.
    - Public comment period closed on July 16, 2010
    - Policy Rewrite Subcommittee reviewed all feedback and developed additional modifications to the proposal for the full committee to review during this meeting.
    - Additional modifications were also recommended during the meeting. A final vote to take the proposal to the Board of Directors for consideration during its November 8-9, 2010 meeting will be completed electronically.
  - Remove the list of frequently transmitted disease from OPTN Policy and instead develop a guidance document that can be updated more frequently and easily.
    - Staff has begun drafting a guidance document (based partially around language removed from Policy 4.0) that will be reviewed by the committee on an upcoming conference call. Plans are underway to present this document to the Board along with the policy rewrite effort in November.
  - Produce a DTAC newsletter twice per year for OPTN members to share information regarding disease transmission concepts.
    - New members for the Newsletter Subcommittee were recruited during the meeting. This group will publish its second edition in November 2010.
    - The next issue is expected to cover topics including Coccidioidomycosis, the importance of reporting potential malignancy transmissions, and a blinded case review to help members who have not yet been involved in a potential disease transmission review better understand the process.
  - Conduct a follow-up survey of all OPOs regarding current screening practices to determine how practices have changed based upon changing test kit availability and the new CDC/US Public Health System guidelines that are expected in Fall 2010.
    - New members were recruited to participate in this process.
    - Timeline for releasing this survey is expected to be delayed based upon a delay in the CDC's efforts to update the current high risk guidelines.
  - Publish disease transmission data in journals, abstracts and at professional meetings to increase community awareness of disease transmission.
    - The Committee continues to publish and present its work, most recently at the American Transplant Congress, NATCO and The Transplant Society.
  - Produce OPTN/UNOS guidance documents based on bacterial transmissions, TB transmissions, fungal transmissions and malignancy to promote practices that reduce disease transmission.

- The Committee received updates on each of these projects, as they continue to develop based upon review of the aggregate potential transmission data collected in each of these areas.
  - Review potential donor-derived transmissions since HTLV screening requirements were eliminated in November 2009 and develop a guidance document to help OPOs and transplant centers understand: (1) when to report a potential HTLV transmission to the Patient Safety System, and (2) what confirmatory testing is available and appropriate.
    - A new subcommittee has been formed to pick up where this work was left in October 2009 and finalize the guidance document for Board review in 2011.
- 3. The Councilor from Region 5 presented his region's recommendations regarding donor nucleic acid testing for committee consideration. Based upon upcoming changes to the US PHS Guidelines, the committee does not believe that such changes to OPTN policy are warranted at this time.
- 4. The Committee completed its semi-annual review of potential disease transmission events reported to the Patient Safety System. Eighty-one cases were reviewed and classified based upon the probability of donor-derived transmission.
  - Of these cases, nine were classified as proven transmissions.
  - After wrestling with how to best classify a number of cases marked as possible during the initial review, members agreed upon the creation of a new classification, "Unlikely." This classification will be defined as "inadequate testing to definitively exclude transmission and no documented disease, but clinical circumstances *make diagnosis unlikely*."
- 5. Dr. Michael Nalesnik, Malignancy Subcommittee Chair, presented an update on the Subcommittee's draft manuscript that is meant to provide guidance to the transplant community by categorizing relative tumor-independent transmission risk when considering a donor. The Subcommittee populated risk categories with individual tumors according to the best data available. The Chair is currently seeking publication, and conferring with various transplant and oncology journals.
- 6. UNOS Research Staff presented data the Committee requested during its April 14, 2010 meeting regarding:
  - An updated report on donor-related malignancies reported on follow up forms but NOT to the Patient Safety System; and
  - Recipients of organs from living donors that died from cancer.
- 7. Committee members received updates from each specialty group on ongoing efforts to analyze trends and patterns noted in bacterial, tuberculosis and fungal cases reported to the Patient Safety System. Work is ongoing, and the committee plans to develop manuscripts and/or guidance documents for each of these areas in an effort to educate the transplant community and help prevent potential transmissions based upon what has been learned from cases the Committee has reviewed.
- 8. The committee reviewed responses from each of the organ specific committees regarding its request for each to consider whether current policy adequately addresses recipient needs in cases where emergency re-listing and explants of the transplant organ become critical due to the risk of potential disease transmission. This may be most prominent when invasive cancers are found unexpectedly in donors after transplant of organs. After review, all organ specific committees reported that based this scenario is adequately addressed with the availability of special requests to regional review boards and current status systems in place for some organs.

9. The Committee briefly discussed its October 2008 OPO Survey regarding donor screening and the need to do a follow-up survey based upon changing test availability and the upcoming changes to CDC high risk donor definitions. A request for volunteers to participate in a Survey Subcommittee was announced, with interested members asked to respond to the Chair or Committee Liaison. It was noted that this effort may be delayed due to a delay in the CDC and US PHS completing updates to its high risk guidelines for potential organ donors. The Committee hopes to release this survey in 2011.
10. The Committee discussed the upcoming elimination of a commonly used enzyme immunoassay (EIA) test used to screen potential organ donors for HIV. In order to determine whether the OPO community was aware of this upcoming change to test kit availability, the Committee partnered with the AOPO to send out a brief 4 question survey to all OPOs. One OPO representative on the committee noted that he had already received the survey, so results should be available soon to the Committee.

Dr. Emily A. Blumberg, Chair  
University of Pennsylvania Medical Center  
Philadelphia, PA

Dr. Michael Green, Vice-Chair  
Children's Hospital of Pittsburgh  
Pittsburgh, PA

Shandie Covington  
UNOS Staff/Professional Services Coordinator  
Richmond, VA