

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

**April 14, 2010
Chicago, Illinois**

The OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee met in Chicago, Illinois on April 14, 2010, and considered the following items:

1. Dr. Michael Ison, Chair, welcomed committee members and introduced a new OPTN/UNOS staff member and a new CDC liaison who will be working with the group.
2. The Committee reviewed its 2009-2010 initiatives, and what had been done to meet these goals to date:
 - Evaluate current status of screening and diagnostic testing for donor disease transmission, and recommend appropriate evidence-based OPTN policy concerning donor testing and screening for transmissible disease.
 - HTLV screening for potential donors eliminated in November 2009
 - Policy 2.0 and 4.0 rewrite currently out for public consideration
 - Develop community awareness materials relating to disease transmission concepts.
 - H1N1 guidance for the transplant community
 - First DTAC newsletter released February 2010
 - Malignancy Subcommittee's manuscript is nearing publication
 - Collaborate with the Centers for Disease Control (CDC) to review current definition of high risk donors and incorporate new definition of high risk donors through appropriate evidenced-based OPTN policy.
 - CDC is working independently on this project with an expert panel that includes several DTAC members.
3. The Committee reviewed feedback received thus far on its recommended modifications and additions to the donor, transplant candidate and transplant recipient data collection forms released for public comment on March 5, 2010. Because the public comment period does not end until April 16, 2010 the Committee may have to reconvene via teleconference to review any additional responses that were not available for consideration at the time of this meeting.
4. The Committee reviewed feedback received thus far on its proposed modifications to OPTN Policies 2.0 and 4.0 released for public comment on March 19, 2010. To date, three committees are in support of the proposal as written and Region 10 voted against the proposal. Because the public comment period does not end until July 16, 2010 the Committee may have to reconvene via teleconference to review any additional responses that were not available for consideration at the time of this meeting.
5. The Committee reviewed the remaining nine proposals released for public comment on March 19, 2010, and provided feedback to the OPO Committee regarding its proposal to require the use of a standardized, internal label that is distributed by the OPTN and OPO notification by the transplant center when an organ is re-packaged for reallocation. After discussion, the Committee voted unanimously in favor of the concept outlined by the OPO Committee (*13 in favor, 0 opposed, 0 abstentions*), but requested that the OPO Committee consider concerns related to the actual labeling system it proposed, including:
 - No verification stage built in for 2nd person review and confirmation of what was entered on the label;

- Only one donor identifier appears on the label (the UNOS Donor ID);
 - A recommendation that current technology like bar coding be considered to avoid the potential for human error in entering information; and
 - Colors currently used for pilot program labels are somewhat close and could be easily confused. Please consider reassigning colors, or using colors that are not so close in nature to avoid labeling errors.
6. The Committee's Living Donor Screening Subcommittee Chair provided an update on this group's work to review the Living Donor Committee's current guidance document regarding infectious disease and malignancy screening for potential living donors and provide feedback for future policy development. The Subcommittee met by teleconference on March 17 and April 8 to develop its recommendations to the Living Donor Committee. The Subcommittee Chair shared his group's recommendations, and after brief discussion, the Committee voted in favor of presenting this feedback to the Living Donor Committee (*12 in favor, 1 opposed, 0 abstentions*).

During the Subcommittee's discussion of appropriate screening/guidelines for living donors regarding malignancy, a question arose around any living donors developing post-donation malignancies. UNOS Research staff presented findings related to this question at the full Committee meeting.

7. Statistics regarding hits to the new UNOS Communications e-newsletter/blog, which includes the DTAC's first electronic newsletter, were shared with the Committee. To date, the DTAC newsletter has received more hits than any other page on the blog. Committee members and staff commented on the positive feedback that was received regarding this effort. The Committee plans to release two newsletters per year and future articles on Coccidioidomycosis and cancer/malignancy reporting were recommended.
8. The Committee completed its semi-annual review of potential disease transmission events reported to the Patient Safety System. Eighty cases were reviewed and classified based upon the probability of donor-derived transmission.
- Members agreed to remove the expected/unexpected category for future case consideration.
 - Members suggested that cases be grouped into categories to better focus on process improvements and determine which categories (or even specific cases) should be considered by the Operations and Safety Committee. Examples of these process categories included: communication, repeat testing, and false positive or negative test results.
 - After wrestling with how to best classify a number of cases, 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."
9. The Committee received an update from the Operations and Safety Committee Chair on this group's new focus and charge since the Operations Committee was renamed. An overview of work being done to address vessel monitoring and safety and the development of a related policy modification anticipated for public comment in Fall 2010 were also discussed.
10. Dr. Michael Nalesnik, Committee Vice Chair and 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. After his presentation, the Committee voted unanimously in support of presenting the

manuscript to the Board of Directors as an informational item and pursuing publication in a transplant journal (*13 in favor, 0 opposed, 0 abstentions*).

11. UNOS Research Staff presented data the Committee requested during its September 9, 2009 meeting regarding:
 - Donor-related malignancies reported on follow up forms but NOT to the Patient Safety System; and
 - Incidence of post-transplant malignancies in pediatric recipients and outcomes using donors with a history of cancer.
12. The Committee considered several questions posed by the Ad Hoc International Relations Committee (AHIRC) regarding its proposal to clarify and improve policies on importing foreign deceased donor organs. The AHIRC is seeking feedback from several committees as it works to develop and finalize a public comment proposal that will be released for formal consideration at a later date.
13. Committee members received a brief update 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. Feedback from the bacterial review will be used to respond to a memo from the Membership and Professional Standards Committee regarding possible development of a policy or guidance document regarding a time period to assess for previous positive cultures for donors that were admitted to the hospital prior to donor evaluation.
14. 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.
15. UNOS Patient Safety Staff reiterated the importance of polling the Committee for their expert opinion regarding probability of donor-derived nature of each case after the 45 Day Report is received. Staff announced and briefly demonstrated a new method for polling members.
16. Outgoing members with terms ending in June 2010 were recognized for their service. The outgoing Chair was also recognized for his service and dedication to the Committee and the incoming 2010-2012 Chair and Vice Chair, Drs. Emily Blumberg and Michael Green, were announced.

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