

OPTN/UNOS *Ad Hoc* Disease Transmission Advisory Committee
Report to the Board of Directors
June 28-29, 2011
Richmond, Virginia

Summary

I. Action Items for Board Consideration

- The Board is asked to approve proposed clarifications to HIV-1 and HIV-2 screening language to Policy 2.2.3.2 (Item 1, Page 3).
- The Board is asked to approve guidance for screening and confirmation of HTLV-1 in potential donors and reporting HTLV-1 infection (Item 2, Page 4).
- The Board is asked to consider and approve guidance for reporting potential donor-derived disease transmission events (Item 3, Page 5).

II. Other Significant Items

- The Committee discussed a reported living donor kidney transmission event (Item 4, Page 6).
- The Committee received an update on international efforts regarding biovigilance (Item 5, Page 7).
- The Committee considered an update regarding its tumor classification categories (Item 6, Page 7).
- The Committee reviewed and classified reported potential donor-derived disease transmission events (Item 9, Page 10).
- The Committee reviewed potential donor-derived disease transmission events reported by donor service area (DSA) and region (Item 10, Page 10).

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This report reflects the work of the Ad Hoc Disease Transmission Advisory Committee (DTAC) during its April 6, 2011, meeting in Chicago, Illinois, as well as all monthly case review conference calls held from December 2010 through May 2011.

I. Action Items for Board Consideration

1. Proposed Clarification to Policy 2.2.3.2. The Committee discussed concerns related to deceased donor HIV screening requirements that arose after the January 2011 implementation of changes to Policy 2.0. The Committee's proposed modifications to policy sections 2.0 and 4.0 were approved by the Board of Directors during its November 2010 meeting. The intent of this rewrite of policy was to clarify and/or improve current OPO and transplant center requirements for screening for, communicating and reporting all potential or confirmed donor-related disease and malignancy transmission events. Members agreed that one goal of this effort was to move any language related to donor evaluation and screening out of policy 4.0 and into 2.0. This would place all donor evaluation language up to the point of recovery in one policy section, making locating language easier for OPOs. Though the majority of donor screening language resided in policy section 2.0 prior to the rewrite, much of the language related to HIV screening, including what is now policy 2.2.3.2, was located in Policy 4.0. The list of tests and laboratory requirements for OPOs screening potential deceased donors outlined in what is now policy 2.2.4.1 were essentially unchanged other than to specifically clarify that the use of diagnostic tests for HIV is not permissible. In this section, all potential deceased donors are to be tested for the presence of HIV antibody, using a FDA licensed screening test for Anti-HIV-1 and HIV-2.

During its November 2010 monthly conference call, the Committee discussed an announcement from a large corporation that an enzyme immunoassay HIV-1/HIV-2 test kit that was commonly used by OPOs for donor screening was to be retired in March 2011. This retirement had been discussed within the OPO community for some time prior to the announcement, and most OPOs were prepared for this change. The Committee's 2008 donor screening survey indicated that less than half of the OPOs were using the soon-to-be retired test kit at that time, as there were already indications that the test would soon be eliminated. As a result the Committee was optimistic that this test elimination would not require actions similar to that for HTLV screening in 2009. To follow up on whether OPO community was aware of this upcoming change and prepared to remain in compliance with current OPTN policy that allows only for screening (and not diagnostic) HIV tests for potential organ donors, the Committee partnered with the AOPO to release a short email survey to all OPOs in September 2010. Though not all OPOs completed the survey, the results received overwhelmingly indicated that OPOs were aware and prepared for this change.

After the test kit was eliminated, only one other FDA-approved antibody screening test remained for detecting HIV-1 and HIV-2 in potential deceased donors. In considering options for donor testing, a question arose regarding whether nucleic acid testing (NAT) would be an appropriate alternative. NAT is currently FDA-approved for testing potential deceased donors for HIV-1. A review of

current policies related to this specific area of policy language indicated that, as currently worded, this option may be considered as permissible in Policy 2.2.3.2.

As part of the Committee's rewrite, a more general HIV testing requirement previously located in Policy section 4.0 was moved to section 2.0, and now appears as Policy 2.2.3.2. This policy requires FDA-licensed HIV-1 and HIV-2 screening for all potential deceased donors, but does not specifically indicate that antibody screening is the specific type of test necessary to meet policy requirements. Because this section of policy now appears before the specific list of required tests to be completed by the Host OPO on any potential deceased donor, there is concern that this inconsistency could create confusion within the OPO community. While NAT is FDA licensed for HIV-1 screening, it is not available for HIV-2 screening at this time and does not meet the more specific requirement in section 2.2.4.1 for antibody screening.

The Committee did not intend to allow NAT as a substitution for antibody screening tests to rule out HIV in potential donors. Further, Policy 2.2.4, which appears later in policy, clearly states "All donor laboratory testing must be performed in an appropriately accredited laboratory utilizing FDA licensed, approved, or cleared serological screening tests" and Policy 2.2.4.1 clearly requires "FDA licensed Anti-HIV I, II (diagnostic testing not acceptable)." The Committee did not recognize this potentially confusing language in policy during its proposal development, but wishes to amend this language to eliminate any potential confusion between Policies 2.2.3.2 and 2.2.4.1 to make it clear that its intentions were to maintain the requirement that HIV antibody screening be completed for all potential deceased donors (**see Exhibit A**). The Committee believes that including the term "anti" in the policy language so that it mirrors what is already present in section 2.2.4.1 will more clearly indicate the expectation that antibody testing is required for HIV-1 and HIV-2 screening.

After careful review, the Committee voted to recommend the following resolution to clarify the intent of this policy for consideration by the Board:

***** RESOLVED, that Policy 2.2.3.2 shall be modified as set forth below, effective pending notice to the membership:**

2.2.3.2 All potential donors are to be tested by use of a serological screening test licensed by the U.S. Food and Drug Administration (FDA) for Human Immune Deficiency Virus (Anti-HIV-1 and Anti-HIV-2).

If the sample is qualified, the screening test for HIV is negative, and blood for subsequent transfusions has been tested and found to be negative for HIV, re-testing the potential donor for HIV is not necessary.

Committee vote: 15 in favor, 0 opposed, and 0 abstentions

2. Proposed Guidance for HTLV-1 Screening and Confirmation in Potential Donors and Reporting Potential HTLV-1 Infection. On October 23, 2009, the Executive Committee eliminated the requirement for pre-transplant deceased donor Human T-cell lymphotropic virus (HTLV) 1/2 screening. This policy change was implemented on November 23, 2009. The basis for this decision included considerable organ wastage due to false positive results using HTLV screening tests, the very low prevalence of HTLV-1 in the United States, and the impending lack of availability of an FDA licensed HTLV-1 screening test that could practically be used in most OPO laboratories.

As one of its 2010 goals, the Committee was charged with developing a guidance document to assist OPOs and transplant programs with ongoing testing issues and questions related to HTLV-1 in the

organ transplant community. The HTLV Screening Subcommittee was formed to develop this document. Some OPOs continue to test for HTLV on a case-by-case basis, and there are still questions regarding how to confirm infection or effectively rule out a positive result in donors or recipients. After reviewing the Committee's previous work on this topic, including a journal article¹ outlining the data reviewed as part of the 2009 policy modification process.

The Subcommittee met during a series of conference calls and reviewed:

- specific tests appropriate for screening, monitoring and confirming HTLV 1/2;
- circumstances in which HTLV donor screening may be performed;
- symptom driven testing in recipient;
- management and monitoring of recipients of organs or vessels from confirmed screen positive donors; and
- when to report recipients found to be HTLV-1 positive post-transplant.

This information was compiled into a guidance document meant to aid the transplant community (**Exhibit B**).

The Subcommittee presented the guidance document to the full Committee during its April 6, 2011, meeting. A member stressed the importance of a yearly review of this and any other guidance document developed by the committee in order to keep information current and up to date. Testing availability is ever changing and it is critical that guidance documents be accurate upon review. Concerns were also raised regarding the location of where guidance documents are posted on the OPTN website. Members noted that the current location is not easily accessible- especially if information is needed quickly or in the middle of the night. Staff will determine whether a new website tab can be created specifically for guidance documents or whether they could also be posted in Secure Enterprise for ease of accessibility.

After careful review, the Committee voted to recommend the guidance document for consideration by the Board of Directors:

***** RESOLVED, that the guidance document “Guidance for HTLV-1 Screening and Confirmation in Potential Donors and Reporting Potential HTLV-1 Infection” developed by the Ad Hoc Disease Transmission Advisory Committee is hereby approved, effective June 29, 2011.**

Committee vote: 17 in favor, 0 opposed, and 0 abstentions

3. Proposed Guidance for Reporting Potential Donor-Derived Disease Transmission Events (PDDTE). The Committee reviewed proposed guidance for reporting potential donor-derived disease transmission events (PDDTE). A draft guidance document was prepared to assist members in determining what types of situations should be reported as a PDDTE for review during the April 6, 2011, meeting (**Exhibit C**). Creation of this document was a 2010-2011 goal for the committee.

Upon review, a member noted that it may be clearer to the reader if the paper is broken into different sections to address: (1) infectious disease, (2) malignancy, and (3) other disease. A Committee

¹ Kaul DR, Taranto S, Alexander C, Covington S, Marvin M, Nowicki M, Orłowski J, Pancoska C, Ison MG. Donor screening for human T-cell lymphotropic virus 1/2: changing paradigms for changing testing capacity. American Journal of Transplantation 210:207-213, 2010

member recommended reviewing the draft alongside similar guidance from Europe on reporting adverse events, including disease transmissions. It was also noted that when addressing positive preservation fluid cultures in the text, that a reference to reporting only clinically relevant information will be helpful to prevent inundation of staff with extraneous reports.

A statement may be helpful that would remind members that regardless of reporting a PDDTE, any new donor information must be shared with all recipient centers per policy- even if potential disease transmission is not anticipated or suspected. A recommendation was made to follow the European model, which has two different types of reports. Additionally, a suggestion was made to add a reference to the DTAC newsletter that describes when to report potential malignancy transmission in addition to reporting a post-transplant malignancy.

Several Committee members again noted concerns regarding the current location of guidance documents on the OPTN website. It was suggested that a separate tab should be created to make these important reference items more accessible to the transplant community.

After completion of the modifications during the April 2011 meeting, the Committee reviewed this document and voted electronically to recommend the guidance document to the Board for consideration during its June 2011 meeting, recognizing that this document will require regular reviewing and updating for it to be useful and relevant to the transplant community.

***** RESOLVED, that the guidance document “Guidance for Reporting Potential Donor-Derived Disease Transmission Events (PDDTE)” is hereby approved, effective June 29, 2011.**

Committee vote: 15 in favor, 0 opposed, and 0 abstentions

II. Other Significant Items

4. Reported Living Kidney Donor HIV Transmission. The CDC’s March 18, 2011 Morbidity and Mortality Weekly Report (MMWR) and a New York State Department of Health Advisory related to a reported transmission of HIV from a living donor to a kidney recipient were reviewed by the Committee during its April 2011 meeting. Both of these documents included specific recommendations for prevention and screening of HIV infection in potential living donors. Currently there is no specific policy language related to screening potential donor organs for conditions that may be transmitted to recipients, though there are guidelines that recommend testing for both living kidney and liver donors.

During the spring of 2010, the Committee formed a Living Donor Screening Subcommittee to provide recommendations to the Living Donor Committee regarding testing that it believed should be required for all potential living donors. This information was shared with the Living Donor Committee in a June 30, 2011 memo (**Exhibit D**). Last year, all potential policy language under development and consideration by the Living Donor Committee was shared with a Joint Societies Working Group consisting of representation from the American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS) and NATCO- The Organization for Transplant Professionals. This group was given a year to consider all of the language to date, as there were concerns that there was concern that some of this potential policy language may dictate medical practice. The Joint Societies Working Group is in the late stages of its review and will report its recommendations to the OPTN before the Living Donor Committee considers these recommendations to complete the policy development process.

The Living Donor Committee requested assistance from the DTAC in developing policy related to potential living donor screening. Any language proposed by this Committee will include input from the Living Donor Committee as well as the Joint Societies Working Group.

The Chair recognized that timelines for potential living donor screening were not included in the Committee's original recommendations memo. Because screening timeline was so critical in the case outlined in the MMWR, this is an area that may be considered in the policy development process. Members noted that there is very little standardization in the area of living donor screening currently, perhaps due to the lack of policy requirements in this area.

Concerns related to implementation of a seven day window for living donor screening, as recommended in the MMWR, were voiced by multiple members. Issues related to time constraints and psychological stresses related to false positive test results were also briefly discussed. Members also questioned whether screening or diagnostic testing would be most appropriate for this population, as what is required for potential deceased donors may not necessarily be appropriate for potential living donors due to the differences in both donor health status and time available to complete testing.

A recommendation was made to re-establish the Living Donor Screening Subcommittee to use the June 2010 memo as a starting point for updated recommendations based upon this recent transmission. Several members noted their interest in participating in this process.

5. Update on International Efforts Regarding Biovigilance. Committee members heard an overview of the World Health Organization's (WHO) current work related to biovigilance (**Exhibit E**). Members learned about how potential donor-derived disease transmission events were reported and tracked in several European countries. Several members of the Committee are actively involved in these global discussions and will continue to update this group regarding progress made.

Several European countries recently approved policy requiring reporting of potential PDDTE. Australia has a similar system under development for research purposes. It was suggested that the Committee consider the distinction between severe adverse events versus severe adverse reactions. This somewhat corresponds to the OPTN system of collecting patient safety events versus PDDTE, but would perhaps provide the Committee with a clearer denominator regarding the risk of potential disease transmission in organ transplantation. Members noted that current staffing assigned to patient safety case intake would not be adequate to address a system that involved the anticipated increase in reporting that adoption of such a system would create.

The primary classification system for PDDTE in Europe is similar to what is used here in the U.S., but uses a number scoring system to determine probability that the event might occur again and also categorizes the significance of the event (**Exhibit F**). These three categories are used to give each report a score that would determine whether local response is required or whether a more significant effort is necessary to promote patient safety.

Committee members agreed that harmonizing this case review process with what is done internationally is beneficial, and that some of the language utilized in the European model may be beneficial for incorporation into the guidance document for what should be reported as a PDDTE.

6. Update of Tumor Classification. Dr. Michael Nalesnik updated the Committee regarding recommended changes to the current case classification system and how it might be modified to better reflect neoplastic events (**Exhibit G**). The classification system was developed with infectious disease as a primary focus, and the Committee has attempted to use these infectious disease-based

categories to also track potential malignancy transmissions. In the case of neoplasm, the clinical event often presents with cancer in the donor rather than in the recipient. The recipient then remains at risk for the development of cancer. Intervention such as resection of tumor is difficult to recognize with the current terminology. Additionally, tumors may develop in an allograft organ de novo post-transplant. The Committee has struggled with how to draw a finite line to distinguish donor-derived versus donor transmitted disease.

In the case of donors with a history of cancer, a risk is implied because of the possibility of circulating dormant cancer cells. A recommendation was made to specifically document which reported donors have this history statistically identifiable from those with active cancer, though difficulty in always having accurate donor information was recognized.

The decision of when to classify a case as “excluded” was also noted as difficult to apply upon review. A recommendation was made to consider a suspected transmission event to exist when there is evidence of donor malignancy, and to introduce terminology within the existing classification categories to recognize a lack of tumor development in recipient(s) despite known tumor or tumor history in a donor. Additionally, a time interval was suggested to recognize that malignancy risk is not as finite as many infectious diseases. Rather than using the standard 45 day follow-up period exercised for most reported potential donor-derived disease transmission events, malignancy cases could be “excluded at six months” or “excluded at final follow-up.”

Committee members continued to discuss whether a specific time period should be outlined to classify potential malignancy transmissions as donor transmitted versus donor-derived. All tumors arise from donor cells that were presumably present in the organ at time of transplant, but evidence-based medicine indicates that anything over 10 years post-transplant be regarded as post-transplant de novo (donor-derived), while under five years should be considered cautiously as potentially donor-transmitted. It was recognized that tumor growth rates can vary greatly.

Pre-transplant resection of donor tumors is also problematic to classify. Most commonly this is seen in renal cell carcinoma resections of donor kidneys. Members discussed the effectiveness of resection as “treatment” of local disease. It was suggested that this treatment might best be classified as “intervention without documented transmission (IWDT).” Such an approach might allow more meaningful analysis of specific interventions while assessing the underlying risk for other recipients and does not require the addition of another malignancy-specific category.

After discussion, the Committee agreed to test the modifications to the case classification list that will more clearly represent both infectious disease and malignancy transmissions (**Exhibit H**) for the next six months. This new list, combined with modifications to policy that allow for case follow-up beyond 45 days as needed will allow for additional monitoring of possible transmission events and more appropriate classification of reports.

7. Update on Donor-Related Malignancies Not Reported to the Improving Patient Safety Portal in Secure Enterprise. OPTN Staff provided the Committee with an updated report on the number of donor-related malignancies reported on the Post-Transplant Malignancy (PTM) form but not reported as a PDDTE (**Exhibit I**). The Committee originally reviewed this report during its September 2010 meeting, but asked for updated information and follow-up with transplant centers to identify reasons why these cases were not reported.

Post-transplant malignancies reported as “donor related” through the PTM forms with diagnosis date of January, 2007 through December, 2010 were reviewed and cross referenced with cases reported as a PDDTE. A total of 58 cases diagnosed and reported on PTM forms. Twenty of those (35%) were

also reported to the Improving Patient Safety portal. Of 58 donors, there were 169 total recipients, and 25 recipient deaths were attributed to malignancy from 24 individual donors. Staff noted that the median time to diagnosis of those reported to portal was 220 days compared to 993 days (almost three years) for those reported only reported on PTM forms.

Calls were made to two recipient centers where reports were made on a PTM form in the last six months but not reported as a PDDTE. In one case, the malignancy was mistakenly reported as donor-related, but it actually developed as a de novo tumor 19 years after transplant. The second case also involved information mistakenly reported as donor-derived when the tumor developed on the recipient's native kidney.

There continue to be some cases reported as donor-related tumors on PTM forms but not reported to PSS, but improvement seen in past year. The Committee recognized its newsletter article published to review what needs to be reported as a PDDTE as a successful educational effort. A recommendation was made to update the UNetSM definition of donor related malignancy. Staff recommendations included:

- Donor Related: If the malignancy is donor related, select yes. If not, select no. If unknown, select UNK. If Yes is selected, the Donor Related section will be displayed on the Post Transplant Malignancy record.
- Tumors transmitted from the donor: In most instances the donor does not have a history of cancer and transmission of cancer is unexpected. This occurrence is usually discovered when multiple recipients of organs from a single donor develop the same cancer (e.g. Melanoma). It may also occur when the clinical (not histological) diagnosis of primary brain cancer is made when, in fact, the donor had a metastatic brain cancer from an occult (concealed from observation) primary site.

8. Summary of Renal Cell Carcinoma (RCC) Cases Reported to the Improving Patient Safety Portal. OPTN Staff reviewed 69 RCC cases that were reported as potential donor-derived disease transmissions between 2006 and 2010 to compare donor cause of death, age, and disposition/outcome of organs was obtained on all deceased donors recovered during this time period (**Exhibit J**). Case numbers ranged from 7 in 2006 to 19 in 2008. The largest specific category of tumor size included 24 cases of reported tumors ranging in size from 1.0 to <2.0 cm. As expected none of the RCC cases involved pediatric donors, and the donor age in the RCC cases tended to be older than in the overall group. The highest percentage of donors (57%) was reported with CVA (stroke) as cause of death.

Sixty-one (or 44%) of the 138 potential kidneys from these 69 donors were transplanted. Several RCC cases were reported for malignancies found in the recipient post-transplant. The majority of those cases reported larger tumors (1.0 <2.0cm).

Additional organs were collected from a number of these donors with RCC, including 49 livers, 16 hearts, and 11 lung transplants. Recipient outcomes for these patients, as well as the kidney recipients, will be collected for future consideration to determine whether donor-derived or donor-transmitted malignancy occurred in these recipients and, if so, when malignancy occurred.

A recommendation was made to collect additional information on whether the tumor was excised before transplant in the patient safety database. This will provide more meaningful data when considering these overall results in the future. Staff anticipates the ability to enter this information retrospectively for cases starting at least in 2008 where more detailed information was collected. Additional data points will be added to the patient safety database, including: number of tumors, size

of tumors, whether or not it was resected before transplant, when the tumor was located, and recipient outcomes by organ, history of donor cancer.

9. Review of Reported Potential Donor-Derived Disease Transmission Events. The Committee completed its semi-annual review of potential disease transmission events reported to the Patient Safety System. Seventy-six cases were reviewed and classified based upon the probability of donor-derived transmission. Of these cases, nine were classified as proven transmissions. A summary review of all cases reported in 2010 indicated 18 cases classified as proven.

It was recognized that the CDC Ex Officio representative on this Committee has returned to the roster and is again receiving case emails. CDC representatives are not participating in committee meetings until their working relationship is finalized with HRSA.

Committee members also discussed new challenges discovered during case review. Areas of concern included:

- the use of tests not approved for screening potential deceased donors and how results should be shared with and considered by transplant programs (*it should be noted that these tests were not required by current policy but additional testing that an OPO was completing by choice*);
- research testing- should unverified results be shared with transplant programs, and how are they to be interpreted/utilized; and
- tracking reported events that may not necessarily need full committee assessment as a potential donor-derived disease transmission event.

The Committee will discuss these issues in greater detail in the coming months and will develop subcommittees as needed to address concerns. It was noted that AOPO has developed the Organ Donation Research Consortium, a multidisciplinary group interested in organ donor research. This group has subcommittees that are currently considering consent of organ donors for research purposes. This group hopes to give comment from an organ donation and OPO perspective on proposed research that involves organ donors. All committee members were asked to put those individuals interested in this type of research in touch with the Consortium through Dr. Dan Lebovitz, AOPO, or the website: www.theodrc.org.

Overall, the Committee will encourage all that they encounter attempting research involving donors or donor testing to do so in a responsible fashion that does not confuse transplant programs by providing results that may not be of any relevance to the donation and transplant process.

10. Review of Potential Donor-Derived Disease Transmission Events Reported by Donor Service Area (DSA) and Region. OPTN Staff provided information regarding the number of cases reported by DSA (de-identified) in order to identify those OPOs with fewer or greater cases reported to the rest of the United States (**Exhibit K**).

A total of 568 potential transmission events have been reported since the Improving Patient Safety portal was implemented in March 2006 through December 2010. Region 5 has reported the largest number of cases, at 112. Region 3 followed, with 100 cases reported during this time period. Region 1 has reported the fewest cases during the time period with a total of 8. The next smallest reporters are Region 6 with 23 and Region 8 with 22.

When reviewing reporting data for 2010, there were 14 out of 58 DSAs with no reports. Two DSAs reported 17 cases each during this same year. Region 5 had the highest number of cases reported for the year, at 34. No donors recovered from Region 1 resulted in a case for DTAC review in 2010.

In looking more specifically at the DSA level, there is one OPO with no cases reported during the five year period of review. The greatest number of reports by a DSA is 43, followed by 39 for another DSA. When considering reporting by donor volume, seven of the eleven regions had reporting ranging from 1.5 to 1.9% of their recovered donors. Somewhat lower reporting was seen in the remaining four regions, which ranged from 0.6 to 1.1%.

For all deceased donors recovered in 2008-2009, DSA reporting of cases as a percentage of all donors recovered ranged from zero for nine DSAs, to over 5% in the DSA with the highest percentage.

Members agreed that this information should be shared during the respective regional meetings for educational purposes. A suggestion was made to separate malignancy versus infectious disease reports. Additionally, a member recommended that committee member representation in these various regions be tracked- is reporting greater in areas where there is direct Committee representation? It was noted that because this committee is ad hoc and not a standing committee. As such, representation is not required from each region; however, all regions will be represented as of the 2011-2012 roster. An update will be provided during the next face-to-face meeting.

11. Confidential Medical Peer Review Subcommittee Update. The Committee received an update from its Confidential Medical Peer Review Subcommittee and learned about a resource (**Exhibit L**) developed by staff to assist members in preparing educational materials, presentations and other publications without compromising the protections afforded to both reporting members and committee members by the confidential medical peer review process.

Several committee members shared concerns that these protections may prohibit or slow the process for community education if new or time sensitive information (i.e. Influenza A subtype H1N1) is critical for circulation based upon a case review. Members noted that the inability to share specifics will potentially harm the ability to publish in journals and further educate the transplant community. Staff noted that time sensitive patient safety matters would be considered on a case-by-case basis in order to promote patient safety while still protecting the confidential medical peer review process. This will be an ongoing effort, with communication between staff and the committee.

12. Encephalitis Subcommittee Update. The Encephalitis Subcommittee Chair presented an update on this group's work to the full Committee, including an abstract (**Exhibit M**) to be presented at the May 2011 American Transplant Congress and plans to develop a guidance document meant to aid the transplant community when considering potential deceased donors with signs or symptoms of encephalitis.
13. Preliminary Efforts to Update the Electronic Reporting Portal. OPTN patient safety staff briefly outlined preliminary efforts to update the Improving Patient Safety portal available to members for reporting: (1) potential donor-derived disease transmissions; (2) patient safety situations; (3) living donor adverse events; and (4) best practices. Several departments will be working together to develop updates to the portal that will streamline the reporting process and provide staff with more detailed information regarding incoming reports.
14. Review of Policies and Bylaws Issues for Public Comment. The Committee reviewed the six policy proposals released for public comment on October 1, 2010 during its December 9, 2010, teleconference.
 - 1) Proposal to Require Collection of Human Leukocyte Antigen (HLA) Type for Thoracic Organs (Thoracic Organ Transplantation Committee)

Upon review, the Committee determined that it had no comment regarding this issue.

- 2) Proposal to Clarify Adult Heart Status 1A Language to Enable Consistent Interpretation of Policy and Reflect Current Programming in UNetSM (Thoracic Organ Transplantation Committee)

Upon review, the Committee determined that it had no comment regarding this issue.

- 3) Proposal to Clarify which Transplant Program has Responsibility for Elements of the Living Donation Process and to Reassign Reporting Responsibility for Living Donation from the Recipient Transplant Program to the Transplant Program Performing the Living Donor Nephrectomy or Hepatectomy (Living Donor Committee & Membership and Professional Standards Committee)

The Committee discussed this proposal and voted to support it as written with no additional comment (13-Support, 0-Oppose, 0-Abstain).

- 4) Proposal to Establish Qualifications for a Director of Liver Transplant Anesthesia in the OPTN Bylaws (Membership and Professional Standards Committee)

Upon review, the Committee determined that it had no comment regarding this issue.

- 5) Proposal to Modify the Requirements for Transplant Hospitals that Perform Living Donor Kidney Recoveries (Membership and Professional Standards Committee)

Upon review, the Committee determined that it had no comment regarding this issue.

- 6) Proposal to Prohibit Storage of Hepatitis C Antibody Positive and Hepatitis B Surface Antigen Positive Extra Vessels (Operations and Safety Committee)

The Committee thought that the restriction from storing all Hepatitis C antibody positive and Hepatitis B surface antigen positive vessels was an appropriate step to promote patient safety and avoid potential disease transmission as a result of human error. After review and brief discussion, the Committee voted to support the proposal as written. (13-Support, 0-Oppose, 0-Abstain)

The Organ Procurement Organization and Membership and Professional Standards Committees' Proposed Model for Assessing the Effectiveness of Individual OPOs in Key Measures of Organ Recovery and Utilization, released for public comment on January 21, 2011, was not reviewed. The committee had no comment regarding this proposal.

The Committee also reviewed the thirteen proposals released for public comment on March 11, 2011, during its April 6, 2011, meeting in Chicago.

- 1) Proposal for Improved Imaging Criteria for HCC Exceptions (Liver and Intestinal Organ Transplantation Committee)

Upon review, the Committee determined that it had no comment regarding this issue.

- 2) Proposal to Reduce Waiting List Deaths for Adult Liver-Intestine Candidates (Liver and Intestinal Organ Transplantation Committee)

Upon review, the Committee determined that it had no comment regarding this issue.

- 3) Proposed Committee-Sponsored Alternative Allocation System (CAS) for Split Liver Allocation (Liver and Intestinal Organ Transplantation Committee)

Upon review, the Committee determined that it had no comment regarding this issue.

- 4) Proposal to Encourage Organ Procurement Organizations (OPO) to Provide Computed Tomography (CT) Scan of Requested by Transplant Programs, and to Modify Language in Policy 3.7.12.3 for Currency and Readability (Thoracic Organ Transplantation Committee)

Upon review, the Committee determined that it had no comment regarding this issue.

- 5) Proposal to Require Updates of Certain Clinical Factors Every 14 Days for Lung Transplant Candidates with Lung Allocation Scores (LAS) of at least Fifty, and to Modify Policy 3.7.6.3 for Currency and Readability (Thoracic Organ Transplantation Committee)

Upon review, the Committee determined that it had no comment regarding this issue.

- 6) Proposal to Allow Outpatient Adult Heart Transplant Candidates Implanted with Total Artificial Hearts (TAH) Thirty Days of Status 1A Time (Thoracic Organ Transplantation Committee)

Upon review, the Committee determined that it had no comment regarding this issue.

- 7) Proposal to Improve the Reporting of Living Donor Status (Living Donor Committee)

After review, the Committee chose not to vote on this proposal because it does not have the expertise to respond to the practicalities of meeting such a policy requirement. It was noted none of the data other than cause of death would benefit the Committee's potential donor-derived disease transmission case review process. Recognizing that collecting additional data may be very difficult for transplant centers that recover living donors, additional information regarding potential living donor-derived disease transmission (e.g. development of malignancy within the established two-year follow-up period) would be beneficial to the DTAC's charge.

- 8) Proposal to Improve the Packaging, Labeling and Shipping of Living Donor Organs, Vessels and Tissue Typing Materials (Living Donor Committee)

After review, the Committee chose not to vote on this proposal. It was noted that the Living Donor Committee should address issues related to:

- Transportation of organs (NOTA makes OPOs responsible for transport of organs, should this be the case for living donor organs as well?)
- Labeling of vessels (the Committee believes that vessels should be labeled in the same way that donor organs are- both on the external triple barrier and the innermost container or bag that holds the organ)
- Keeping this policy updated as deceased donor organ policies are updated.

The Committee suggests consistency to minimize contamination of organs, and standardizing the overall process as much as possible between deceased and living donor organs for consistency and simplicity within the transplant community.

- 9) Proposal to Require Confirmatory Subtyping of Non-A₁ and Non-A₁B Donors (Operations and Safety Committee)

Upon review, the Committee determined that it had no comment regarding this issue.

- 10) Proposal to Standardize Label Requirements for Vessel Storage and Vessel Transport (Organ Procurement Organization (OPO) Committee)

After hearing the presentation, the Committee had a number of questions. It was recognized that if only the outermost layer of the triple sterile barrier is labeled, there would be no requirement for a label on the actual jar that holds the vessel. This would produce an opportunity for patient safety to be compromised. Without a label on the rigid container that holds the vessels, there is no information available to OR staff during time out procedures meant to promote patient safety. Labeling this internal container at the transplant center introduces opportunity for omission of important information (such as HCV or HBV positive donor status, as seen in at least one donor-derived disease transmission event) or transcription errors regarding donor ID or blood type. Members suggested that requiring an internal and external label would be more appropriate, as the triple sterile outermost barrier/bag is frequently discarded and not kept with a stored vessel.

After discussion, the Committee voted unanimously to oppose this proposal as written (0-Support, 17-Oppose, 0-Abstentions). Committee members believe that OPOs should provide the same type of labeling for vessels as what is required for organs. The Committee recommends that this proposal be modified to require that both the external triple barrier and the internal rigid container in which the vessels are actually stored be labeled by the OPO prior to shipping.

- 11) Proposal to Update and Clarify Language in the DCD Model Elements (Organ Procurement Organization (OPO) and Organ Availability Committees)

Upon review, the Committee determined that it had no comment regarding this issue.

- 12) Proposal to List All Non-Metastatic Hepatoblastoma Pediatric Liver Candidates as Status 1B (Pediatric and Liver and Intestinal Organ Transplantation Committees)

Upon review, the Committee determined that it had no comment regarding this issue.

- 13) Proposal to Eliminate the Requirement that Pediatric Liver Candidates Must be Located in a Hospital's Intensive Care Unit to Qualify as Status 1A or 1B (Pediatric Transplantation Committee)

Upon review, the Committee determined that it had no comment regarding this issue.

15. Review of 2010-2011 Goals as Assigned by the Board. 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.**
 - The Committee's rewrite of these policy sections was approved by the Board of Directors during its November 2010 meeting, and implemented on January 10, 2011.
- **Remove the list of frequently transmitted disease from OPTN Policy and instead develop a guidance document that can be updated more frequently and easily.**

- The Committee will present this document to the Board of Directors during its June 2011 meeting.
- **Produce a DTAC newsletter twice per year for OPTN members to share information regarding disease transmission concepts.**
 - This communication tool continues to be used effectively, and receives positive feedback from the transplant community.
- **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.**
 - The timeline for releasing this survey remains on hold, as it is dependent on 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 in a number of professional journals and meetings, both nationally and internationally.
- **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.**
 - The Committee will present this document to the Board of Directors during its June 2011 meeting for consideration.

16. The Chair recognized the many efforts to educate both the national and international transplant community and share what the Committee has learned as part of its case review process over the past year. This included both oral and poster presentations at the American Transplant Congress, the NATCO annual meeting, the Transplant Management Forum, the Infectious Diseases Society of America (IDSA), the Duerree Congressi in Italy, a World Health Organization meeting on biovigilance, and others. Additionally, Committee members have published in the American Journal of Transplantation and other publications on topics including Chagas, HTLV 1/2 screening, and malignancy outcomes.

17. Members whose terms end on June 30, 2011 were recognized for the service and dedication. Proposed membership for 2011-2012 will include representation from all eleven regions, even though this is not required for ad hoc committees.

**AD HOC Disease
Transmission Advisory
Committee**

MONTH	DEC	JAN	FEB	MAR	APR	APR	MAY
DAY	9	20	10	10	6	14	12
FORMAT (select)	Phone	Phone	Phone	Phone	In Person	Phone	Phone
NAME	COMMITTEE POSITION						
Emily Blumberg MD	Chair	X	X	X	X	X	X
Michael Green MD, MPH	Vice Chair	X	X	X	X	X	X
Carrie Comellas BS, RN, CPTC	At Large		X	X	X	X	X
Afshin Ehsan M.D.	At Large	X		X	X	X	X
Barry Friedman RN, BSN, MBA, CPTC	At Large	X	X		X	X	
Thomas Gross MD	At Large	Term started 1/2011	X	X	X		X
Daniel Kaul MD	At Large	X	X	X	X	X	X
Bernard Kubak MD, PhD	At Large	X	X	X	X	X	X
Daniel Lebovitz MD	At Large	X	X	X		X phone	X
George Lyon III, MD, MMSc	At Large	X	X	X		X	X
Rachel Miller MD	At Large	X	X	X	X	X	X
Michael Nalesnik MD	At Large	X	X	X		X	X
Timothy Pruett MD	At Large	X	X		X	X	X
Alison Ballew Smith RN, BSN	At Large	X				X	
Lewis Teperman MD	At Large		term ended 12/2010				
J. Elizabeth Tuttle-Newhall M.D.	At Large					X	
Brahm Vasudev M.D.	At Large	X	X			X	
Linda Weiss	At Large	X			X	X	X
Michael Ison M.D.	Ex. Officio	X	X			X	X
James Bowman III, MD	Ex Officio	X	X	X	X	X phone	
Bernard Kozlovsky MD, MS	Ex Officio				X	X phone	X
Shandie Covington BS	Committee Liaison	X	X	X	X	X	X
Kimberly Parker	Support Staff	X	X	X	X	X	X
Sarah Taranto	Support Staff	X	X	X	X	X	
Stacey Burson	Support Staff	X	X	X	X	X phone	
Kimberly Taylor, RN	Support Staff	X	X	X	X	X	X
Lin McGaw, RN, Med	Staff	X	X			X	
Brian Shepard	Staff	X					
Franki Chabalewski, RN	Staff					X	