**OPTN/UNOS *Ad Hoc* Disease Transmission Advisory Committee**
**Report to the Board of Directors**
**June 23-24, 2009**
**Richmond, Virginia**

**Summary**

## I. Action Items for Board Consideration

- None

## II. Other Significant Items

- The Committee received an update from the *Ad Hoc* HTLV Advisory Group regarding this group's progress on how to address the discontinuation of the most commonly used HTLV I/II test kit. Current policy requires this testing, but the elimination of this test kit will make compliance difficult for most OPOs. (Item 1, Page 3)

- The Committee heard a report on the Malignancy Subcommittee's efforts to develop a guidance document for the transplant community to categorize the risk of donor tumor risk transmission. (Item 2, Page 8)

- The Committee received updates on NAT and infectious disease testing surveys and heard reports from the CDC's NAT Yield Study and the recent NAT Consensus Conference. (Item 3, Page 13)

- The Committee completed is semi-annual review of potential disease transmission events reported to the Patient Safety System. (Item 5, Page 15)

- The Committee discussed improvements to case workflow, review of case follow-up reports and draft closing letters for indeterminate or non-transmission cases. (Item 6, Page 16)

- The Committee discussed suggested additions and revisions to the donor, candidate and recipient data collection forms. (Item 7, Page 17)

- The Committee was introduced to plans to create a bi-annual newsletter to report on general concepts and trends that have been recognized as potential transmission reports as reviewed. (Item 8, Page 18)

- The Committee reviewed policies and bylaws issued for public comment. (Item 9, Page 18)

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**Michael G. Ison, MD, MS, Chair**
**Michael Nalesnik, MD, Vice Chair**

*This report reflects the work of the Ad Hoc Disease Transmission Advisory Committee (DTAC) during its May 6, 2009, meeting in Chicago, Illinois, as well as all monthly case review conference calls. Additionally, the Committee's Malignancy, OMB Forms Review, and Newsletter Subcommittees and HTLV Advisory Group and have met by teleconference and LiveMeeting® since the DTAC reported to the Board in November, 2008.*

1. Ad Hoc HTLV Advisory Group Update

The *Ad Hoc* HTLV Advisory Group, chaired by Dr. Daniel Kaul of the University of Michigan, was created by the Committee to address concerns in the OPO community regarding plans to retire a frequently used HTLV-I/HTLV-II EIA assay kit on December 31, 2009 (**Exhibit A**). Currently, testing of donors for HTLV is required for all potential organ donors in the United States (OPTN Policy 2.2.8.1). This Advisory Group was asked to advise the Committee on current options regarding alternate testing methods and whether subsequent changes to OPTN policy language may be necessary. The group includes members from the DTAC, OPO, Operations and Organ Availability Committees, AOPO, CDC, FDA, HRSA, experts in the field of HTLV, as well as representatives from test kit manufacturers and labs that support many OPO's testing needs (**Exhibit B**).

The Advisory Group planned an aggressive timeline to accomplish its work, and share its findings with the DTAC so that the Committee could update the Board of Directors of its progress on addressing the issue during the June 2009 meeting. It met by teleconference on March 17, and April 7, 2009,

During its March 17 meeting (**Exhibit C**), the Advisory Group focused on the following questions:

1. Should HTLV testing continue to be required of all donors? If so, does this information have to be available prior to donation?
2. What is the potential impact of not having HTLV serology data available on all donors at the time of donation?
3. Are there alternative testing platforms or approaches that can be considered?

It was also noted by a Working Group member that HTLV is the current concern, but having a protocol for handling other test kits that will leave the market should also be kept in focus. It was emphasized that OPTN/UNOS and CMS require all OPOs to test potential donors using FDA approved reagents, but compliance is difficult when FDA-approved screening or diagnostic tests are eliminated. Members anticipated that keeping up with changing test availability will be a game of "catch up" unless the community learns how to be proactive in addressing these concerns. It was suggested that (1) there is a group within the OPTN/UNOS that is monitoring test kit availability and other viable options for testing, and (2) that this group inform the transplant community and its clients about constantly changing testing availability.

An OPO Committee representative noted the importance of having plans in place for an interim solution because test kits could become unavailable prior to the 12/31/09 date. This has been the case with previous tests removed from the market.

A member suggested setting up consolidated testing labs at high traffic hubs for each region to send samples for PRISM testing and then follow-up NAT confirmation as necessary. It was suggested that this be done as part of a study. Members questioned who would pay for the PRISM machines, the only FDA approved alternative currently on the market, and questioned the logistics of shipping samples and receiving results with an appropriate turnaround time to make running the PRISM machine practical. Members agreed that this was not a practical way of resolving concerns. The maintenance and wasted reagents would almost double the cost of testing for OPOs.

It was noted that both of the commercial labs participating in the Working Group offered to test some HTLV test systems that use research use only (RUO) assays against current Abbott HTLV EIA results by testing archived positive and negative samples as well as prospectively collected samples. The RUO assays may prove to be a short term solution for testing concerns, but have not been FDA approved for use in testing potential donors. RUO assays appear to be the only short term solution to the problem unless the Architect platform (a European test platform that runs smaller batches of tests than the PRISM, and could be potentially more cost efficient and timely for OPOs) can be brought to the U.S., but neither is FDA approved. Without policy changes, neither of these would allow OPOs to be compliant with OPTN/UNOS or CMS requirements. The long term goal would be having alternate test kits in the pipeline for all required donor tests to avoid requiring short term solutions in the future.

Participants considered whether <u>not</u> testing for HTLV is an option for donors? Case reports of donor derived infection leading to disease have been reported. Blood and tissue banks require this testing. Members questioned whether the community is willing to take this risk. OPTN data indicates that there have been 134 donors resulting in transplant organs that were found to be HTLV I/II positive since 1999. This data does not include the number of potential donors that screened as positive and were not used. Short term survival whether receiving positive or negative organs, appears to be more or less equivalent at one year. The data does not include Western Blot results on whether the donor was HTLV I or II positive. The OPTN data and a soon to be published paper from Dr. Marvin will be circulated to the group for consideration. A member questioned that, in the event that testing alternatives cannot be provided in time, is it reasonable for the OPTN to acknowledge HTLV as an acceptable consequence of organ donation and include it in the consent form? Members agreed that policy cannot be written on a liability standpoint alone because no organ transplants would take place. It was noted that a practical and feasible solution must be found.

A Working Group member noted that using testing that is not accepted according to FDA standards is risky from a policy standpoint. UNOS is looking for national testing of organs using a standard that is accepted nationwide. The RUO assays do not currently meet these standards.

In closing, members were asked to suggest additional information needed to advance the discussion regarding HTLV testing, including:

- Incidence data from OPOs that are doing initial screening and, if available, confirmatory testing;
- Validation data from RUO kits (CDC, LABS, Inc. NIT); and
- A list of the various RUO HTLV assays that is available.

The Working Group reconvened on April 7, 2009 (**Exhibit D**) with a goal of reviewing data collected on potential donors to get a better idea of (1) the frequency of positive HTLV I/II screening tests; (2) how

often confirmatory testing was completed after a positive screening test; and (3) how often testing to differentiate between HTLV I and HTLV II infection was pursued in an effort to make a determination on whether HTLV screening should remain mandatory for all potential donors.

Working Group members reviewed a spreadsheet detailing redacted results from seven OPOs and/or labs that provided information on 14,432 organs tested for HTLV I/II.

- Of these 14,432 tests, only 150 (1.04%) resulted in a positive screening test.

- Three of the seven labs followed up positive results with confirmatory testing. Of the 108 positive tests that were followed by confirmatory testing:
  - 56 were positive
  - 30 were negative
  - 22 were indeterminate

- Only one of the OPOs/labs differentiated between HTLV I and HTLV II. It was noted that this lab did not complete this testing for all samples, but most were reviewed. Of the 21 samples tested, only one specimen was confirmed as HTLV I, for a rate of 0.03%.

**HTLV Screening Rates Among Potential Organ Donors**

| HTLV Screening Test Positive (7 OPOs/labs) | Follow-Up Confirmatory Test Positive (3 OPOs/labs) | Further Differentiation to Prove HTLV I Positive (1 lab) |
|---|---|---|
| **150/14432** | **56/11003** | **1/3490** |
| **1.04%** | **0.5%** | **0.03%** |
| **total positives** | **confirmed** | **proven positive HTLV I** |

In reviewing the data supplied by these seven OPOs and/or labs, one could generalize that:

For every **10,000** potential organ donors there would be:

**100** positive screening tests

⇩

**50** positive confirmatory tests

⇩

**1-10** HTLV I positive donors (estimated)
The rest of the positives would be HTLV II

This would result in approximately 100 donors likely being ruled out or their organs discarded, when only 1-10 are likely to actually have HTLV I. The 90-99 donors ruled out unnecessarily out of every 10,000 potential donors would carry no risk of transmitting HTLV I.

To put HTLV testing concerns into perspective, Drs. Ison and Kaul suggested to compare HTLV I to West Nile Virus (WNV) which has similar neurologic sequellae and EBV in which there are similar

malignancy risks. Published data indicates that the prevalence for West Nile virus in organ donation is 0.024%. Based on current data, the prevalence of HTLV I/II in blood donors is 0.035-0.046% and in organ donors is 0.003-0.5%. Currently, testing is not required for WNV in part because of the concern that the risk of false positive results will result in more organ loss than disease prevention through the use of the test.

Two obvious outcomes to HTLV I were pointed out, with the following risks:

- No infection, which is unlikely
- Infection
    - Low but possibly present risk of leukemia or lymphoma (delayed onset)
    - Risk of HTLV-associated tropical spastic paraparesis (TSP) (onset can be closer to transplant)

The Advisory Group then reviewed OPTN data regarding the recovery and transplantation of deceased donor organs from HTLV I/II positive donors in the U.S. from 1999 through 2008. There were a total of ten recipients of HTLV+ organs with malignancy reported post-transplant:

| Organ Received at Transplant | Malignancy reported post transplant |
|---|---|
| Heart | Squamous cell skin cancer |
| Kidney (x 2 recipients) | Lung cancer |
| | Basal cell skin cancer and melanoma |
| Liver (x 7 recipients) | Recurrent HCC |
| | Juxtapapillary chorodial melamona in left eye |
| | Mandicular, type squamous cell |
| | Basal cell skin cancer |
| | Three reported squamous cell skin cancer |

**Neurological problems were not collected in this data set.*

After considering the information presented, a Working Group member noted that there appears to be more of an issue with the number of donors lost than the number of recipients at risk for cancers or TSP. She questioned whether additional testing for HTLV is warranted, especially considering the delay in developing these symptoms?

An OPO representative suggested that it makes little or no sense to pursue a different serological test for HTLV (i.e. RUO tests) that may be even less reliable than the bench kit currently being used after reviewing this data. He worried that the number of false positives would increase and more organs would be lost when the incidence of actual infection is so very low and the incidence of clinical sequelae from clinical infection is even lower. He recommended removing the HTLV testing requirement in the short term because access will be severely limited due to the discontinuation of the current bench kit. Long term policy changes might consider NAT and other technologies beyond that as they become available to more OPOs. It was noted that there are many infectious disease that are not tested for whether this be due to test kit availability or turnaround time appropriate for organ donation and transplantation. WNV is an example of such a disease that affects transplant recipients.

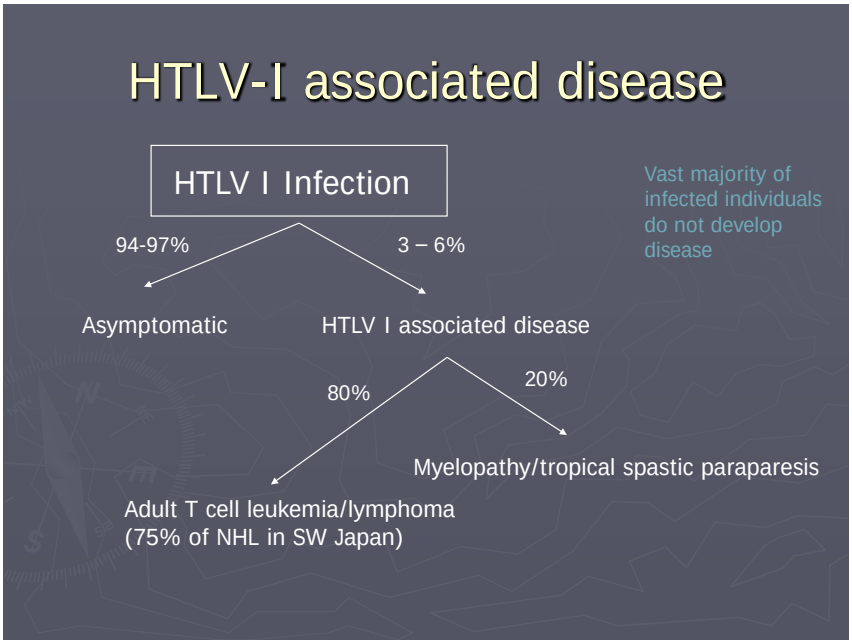
Another member suggested that retrospective testing might be a prudent alternative for informed consent. The test will still exist, but it will not be available for many in a prospective fashion to avoid post-transplant morbidity. Retrospective analyses could be batched and sent out for PRISM testing. It was also noted that tissue donation testing would also provide HTLV I/II results in cases where tissue was also recovered. EBV testing is already retrospectively completed at some centers. Retrospective donor samples for those that are not already tissue donors would be a definite possibility, but coordination is key

to make sure that the sample is used for all testing and that this sample is not hemodiluted. Removing the time consideration from policy will also allow for confirmatory NAT testing for HTLV I and II to be completed.

Dr. Kaul updated the full Committee regarding the *Ad Hoc* HTLV Advisory Group's efforts during its May 2009, meeting in Chicago (**Exhibit E**). Though HTLV I/II testing is currently required on all potential donors using an FDA approved testing kit, there will not be a practical HTLV I/II test available for most OPOs by the end of this year. The elimination of the most commonly used EIA testing kit by its manufacturer on 12/31/2009 in favor of a high throughput, far more expensive platform that is not practical for screening potential organ donors has triggered the need for the OPTN to consider:

- Should HTLV testing continue to be a requirement for all donors?
- What is the potential impact of not having HTLV serology data available at the time of donation?
- Are there alternative testing platforms or approaches?

It was noted that the majority of individuals infected with HTLV do not develop disease, though a significant minority, 3-6% do develop HTLV I associated disease, usually over a number of years. Serious disease can develop and are not easily treated. HTLV II is more common than HTLV I, but has not been associated with human disease.




Possible strategies to pursue once the current EIA test kids are no longer available include:

- Use the only remaining FDA approved test, the Abbott PRISM platform, which is extremely cost prohibitive and not practical for many OPOs.
- Discontinue requirement for testing prior to transplant.
- Pursue retrospective testing and follow-up algorithm to include nucleic acid based or Western Blot testing to confirm or rule out any initially positive test results for recipients.
- Utilize RUO assays?
    - Regulatory barriers - not FDA approved for this type of testing and based on current FDA regulations, manufacturers are not allowed to sell to labs if they know the test system will be used for clinical diagnosis.

- Best assay to use

The Subcommittee will reconvene one more time to formalize its recommendations to the Committee later in May. Plans are in place to have the Committee vote on final recommendations at its May 21 conference call (or a separate conference call if needed), and then take these recommendations to the Board in June.

Members discussed whether retrospective testing at a consolidated lab that could run the PRISM platform for weekly or monthly batched runs would be practical and appropriate. Information structures are already in place for sharing retrospective test results from the OPO to recipient centers, i.e. CMV and other common tests. Blood and tissue banks will continue to test for HTLV and will not have problems with employing the PRISM platform because of the larger number of samples to be run and the flexibility in time constraints as compared to that of organ donation.

Additionally, concerns were raised regarding how to tell recipients that they are HTLV I positive, as there is no successful treatment for this diagnosis. If the incidence of disease is approximately 0.03%, and an educated guess of the number of transmissions without pre-transplant testing based on this figure would be expected as one case every few years, a member questioned whether even retrospective testing is necessary.

Another recommendation was to have the retrospective testing be a time-limited policy. A recommendation could be made to perform HTLV testing retrospectively as a variance for a period of time (perhaps a year), and then study the data to determine if policy modifications are appropriate. Another option would be to track post-transplant testing on a form to determine whether eliminating this requirement is appropriate. A member noted that it would take years to get meaningful data based on the 0.03% incidence rate.

Careful surveillance would be critical in following recipients and determining whether potential transmission is suspect. The HTLV requirements were more than likely added to policy due to blood and tissue testing requirements. Members questioned whether this is an organ transplant requirement that should differ from blood and tissue banking requirements due to the differences in time requirements for allocation.

If a recipient is known to be HTLV I positive prior to donation, would this be an automatic rule out for donation or would centers have the opportunity to determine whether careful informed consent and transplant would be appropriate in critical patients to prevent immediate death?

The Committee will consider the Working Group's final recommendations and then share its recommendations with the Board in June 2009. From there, appropriate policy modifications could be sent out for public comment and Board consideration prior to the current kit's retirement date. A member also suggested talking with AOPO to determine if any DSAs or regions are experiencing difficulty in obtaining these kits at the current time.

2. <u>Malignancy Subcommittee Update</u>

The Malignancy Subcommittee, chaired by Dr. Michael Nalesnik, met by teleconference on January 23, February 20, and April 14, 2009, to continue its discussion regarding how to best categorize the risk of tumor transmission in organ transplantation.

During its January 23 conference call (**Exhibit F**), the subcommittee focused on work done in the European transplant community on approaching donor tumor transmission, categorizing specific cancers

into specific risk categories. Members worked together to begin making specific decisions on populating the risk categories, once agreed upon, with specific tumor types. Renal Cell Carcinoma (RCC) was recognized for its frequent reports to the Patient Safety System, and an area that this group should work to educate the transplant community on regarding acceptable tumor size in considering transplantation.

The Subcommittee reconvened on February 20 (**Exhibit G**), to further define risk categories and review recent literature regarding RCC. Members discussed how to classify specific tumors into each of the risk categories. It was noted that an open category was created under the medium risk designation to capture tumors not included on the list in which epidemiological data exist to indicate that potential benefit from transplant is much greater than tumor transmission risk (i.e. low-grade GIST). Donors with a history of malignancy were addressed in the high risk category along with a number of other specific cancer types.

The breakdown of CNS tumors was not specifically discussed in detail by this group, and the Subcommittee looked for input from the oncologists of the group regarding the currently assigned categorizations. At present, low grade CNS tumors are placed in the medium risk category and high grade tumors are listed in the high risk category, as was suggested in the Italian model used to develop this draft categorization. Members questioned whether a subset of these high grade tumors should be placed in an "unacceptable" category. Discussion with outside experts may be required to make this distinction.

Subcommittee members reviewed a first draft manuscript put together by Dr. Nalesnik during its April 14 teleconference (**Exhibit H**). All of the discussion and recommendations from the committee were compiled in manuscript format for future publication as a guidance document for the transplant community and possibly a journal article. The College of American Pathologists (CAP) has agreed to informally review the tumor listings in this document to make sure that the classifications of the tumors developed by the subcommittee are appropriate. The subcommittee believes that this is the first of what they hope will be many iterations of this effort. This manuscript is to be seen as a starting point that is expected to provide guidance to the transplant community by defining the areas that are currently known in transplanting organs from donors with known malignancy.

Members agreed that the current 45 day time frame outlined in Policy 4.7 (Post-Transplant Reporting of Potential Transmissions of Disease or Medical Conditions, Including Malignancies) for following cases potential disease transmission in the DTAC is not useful when considering malignancy. Subcommittee members discussed a two year follow-up as appropriate for malignancy cases reported to DTAC, as research indicates that a potentially transmitted malignancy would manifest itself in this time period. This is expected to be addressed in a future public comment proposal. It was noted that regular follow-up is collected in UNet® on all transplant recipients and post-transplant malignancy follow-up forms are completed for any recipient developing post-transplant malignancy. UNOS Patient Safety Staff are using a newly developed internal database that will help flag cases where post-transplant malignancy forms are reported more efficiently for cases of potential disease transmission.

A consensus conference was discussed as a possibility that would be of great benefit to the transplant community as a whole. Members agreed that this paper coupled with careful decision making and informed consent of families could prevent future litigation related to transplanting donor organs with malignancy present.

Subcommittee members expressed their appreciation to Dr. Nalesnik for putting this group's thoughts together in manuscript form. All agreed to carefully review the paper and its tables based on feedback heard during the conference call, and continue to share suggestions and edits. Dr. Nalesnik will update the full committee on the subcommittee's progress and share a second draft of the manuscript during the May meeting.

Dr. Nalesnik presented an overview of the Subcommittee's work to the full committee during the May 6, 2009, meeting (**Exhibit I**) and shared the draft manuscript being developed by this group as a guidance document for the transplant community and also possible publication in a medical, pathology or transplant journal. He noted that the Subcommittee discussed:

- Transmission risk factors for use of organs from donor with tumor or history of tumor;
- Adequacy of existing data regarding donor tumors;
- Evaluation of donors for presence of tumor;
- Resources available to aid clinicians in evaluation of donor tumors;
- Relationship of guidelines to physician practice;
- Suggestions for DTAC involvement with transmission events.

Discussion regarding specific donor consent for specific risk levels and the evaluation of recipients with tumor or tumor history was deferred by this group at present time.

A draft of the current donor tumor transmission risk categories was shared with the Committee. Dr. Nalesnik stated that the Subcommittee used the Italian National Transplant Center's General Criteria for donor eligibility assessment as a starting point and then worked to develop its own format. Features of the proposed Tumor Risk Categorization System include:

- Independent of individual tumor type
- Independent of tumor therapy
- Discrete ordinal mutually exclusive categories
- Simple terminology
- Separate nominal and objective criteria for inclusion depending upon best data currently available (this allows for easy and uniform updating as knowledge evolves)
- Informs but does not directly supersede clinical judgment in individual cases

**DONOR TUMOR RISK TRANSMISSION CATEGORIES (May 2009 DRAFT)**

| Risk Category | | Definition | | Recommended Clinical Use |
|---|---|---|---|---|
| | | Nominal | Frequency estimate (f) | |
| 0 | No significant risk | No active malignant tumor or history of tumor found during evaluation | 0% | Standard |
| 1 | Minimal | Literature suggests minimal risk of tumor transmission | $0\% < f \leq 0.1\%$ | Clinical judgment with informed consent |
| 2 | Low | Literature suggests low-grade risk of tumor transmission | $0.1\% < f \leq 1\%$ | Emergency use with informed consent |
| 3 | Intermediate | Literature suggests significant risk of tumor transmission | $1\% < f \leq 10\%$ | Use of these donors is generally not recommended. On occasion, a lifesaving transplant may be acceptable when expected survival is short. Informed consent necessary |
| 4 | High | Literature suggests high risk of tumor transmission | $> 10\%$ | Use of these donors is discouraged except in rare and extreme circumstances. Informed consent is necessary |
| U | Unknown risk | Evaluation for risk factors is incomplete or no literature exists to assess risk | N/A | Emergency use with informed consent |

After reviewing each of the categories and samples on tumors that fall within each, Dr. Nalesnik noted some of the current limitations to the draft, where the Subcommittee will need to focus its future work:

- Assignment of tumor risk is largely qualitative- considered a starting point awaiting evidence-based data
- No graded informed consent consideration
- No comprehensive recommendations for screening protocols for donors
- Tumor listing is not comprehensive, although it is the most complete list at present (135 separate tumors/conditions)
- Does not address outcomes of tumors, only risk of transmission
- Does not address legal issues

The Subcommittee was asked to make recommendations to the DTAC regarding its work. Dr. Nalesnik shared the following suggestions:

- Extend follow-up of potential tumor transmission cases by DTAC to two years in lieu of the current 45 Day Report completed for all potential disease transmission cases.
    - Communication until acute issues resolved; interim report at 1 year after initial report, final report at 2 years
- Consider adopting risk-based categories for donor tumors.
- Convene a consensus conference based on this Subcommittee's report to discuss issues related to donor malignancies and to include transplant physicians, oncologists, pathologists, OPO representatives, lawyers, and patient advocates.
- Centers should strongly consider testing all tumors (except PTLD) that arise in the first year for donor origin.
    - Formation of web links to donor malignancy resources
- Centers establish a mechanism to ensure that unexpected donor results are reported immediately to donor host OPO which follows with rapid calls to other involved centers.
- Re-emphasis/requirement for early examination of kidneys and notification of donor host OPOs for declined organs prior to discard.
- Include a minimum of four malignancy experts on DTAC to include representation from oncology, transplant surgery, and pathology.

Dr. Nalesnik noted that Subcommittee members are already involved in review of the draft manuscript. He requested Committee members also review this document and provide feedback. In addition to speaking with CAP, a member also suggested communicating with Australian oncology and/or pathology specialists to learn more about their cancer screening related to donation and consent rates to better address skin cancers and melanomas in the Donor Tumor Transmission Risk Categories being developed.

After review and discussion, the Committee requested data on how many potential donors are currently worked up and then aborted or turned down due to malignancy, and what donor malignancy diagnoses most frequently progress to transplant. This data will be presented at the next Committee meeting with the caveat that numbers will not be all inclusive due to the fact that unless a match run is generated for a potential donor, information on aborted donor efforts would not be captured in UNet® for analysis. A suggestion was made to partner with several OPOs to get a clearer picture of the number of potential donors that are not captured in UNet® because their organs are ultimately ruled out for recovery.

Members questioned how this system would be implemented effectively, noting that it is difficult to ascertain a thorough history and pathology for potential donors with previous malignancy. Depending on donor family history is not effective in these instances.

Prostate cancer has still not been specifically defined in the risk categorization due to the limited data available. A member noted that this is frequently seen in the growing population of older donors, and suggested that inclusion would be most helpful to the transplant community. The Subcommittee will continue to review the available literature and work towards an appropriate categorization for this malignancy. Age stratification was suggested to identify where tumors are found most frequently. Data to be reviewed later in the meeting suggested that more tumors were found in younger donors than in older donors, but this may be the result of older adults having more screening for malignancy (See **Exhibit J** as discussed in the next section of this report).

A member questioned if data had ever been collected regarding the percentage of potential donors that have had any history of cancer or malignancy. What number of these potential donors ultimately proceeds to organ recovery? No one was aware of such a data collection, and assumed only anecdotal information exists. A study with partnering OPOs over time would be required to collect such data.

A suggestion was made to include as part of the manuscript, a specific request that transplant centers involve a local oncology services in treatment of any recipient of an organ that may involve potential donor derived malignancy transmission.

<u>Post Transplant Malignancies in Multiple Recipients of Organs from the Same Deceased Donor</u> Ms. Sarah Taranto, UNOS Research Liaison, presented descriptive information requested by the Malignancy Subcommittee on those deceased donors from 2000 to 2007 where more than one recipient of the donor's organs was reported to have a post-transplant malignancy at any time point post-transplant (**Exhibit J**). Details regarding the number of donors identified, types of malignancies, donor age and gender, and times from transplant to diagnosis of malignancy were included. The Committee was interested in utilizing currently collected OPTN data to further investigate potential cases of donor derived malignancies in transplant recipients which may have not been identified as such by the transplant programs. This data may help to educate the transplant community on the true incidence of donor related post-transplant malignancies.

Of the 153,701 recipients transplanted from 2000 through 2007, 8,290 recipients (5.4%) reported at least one post-transplant malignancy. (The 153,701 recipient total is a subset of the 157,438 deceased donor transplants performed in this time frame. After accounting for recipients receiving more than one organ from the same donor, the total was 153,701.)

Just over fourteen percent of the donors transplanted resulted in at least one recipient with a reported post-transplant malignancy. However, only 1.3% (695) of the 52,407 deceased donors resulted in more than one recipient with a malignancy post-transplant. This is the group that was reviewed more closely in response to the Committee's data request.

There were 34 cases with two or more recipients from the same donor where all recipients reported a post-transplant malignancy. In seven of these cases, there were three or more recipients.

Time to first reported malignancy was calculated to determine the very first diagnosis of any malignancy for any of the recipients from a donor. The group of donors with the first malignancy reported two or more years post-transplant accounted for 213 (30.6%) of the 695 donor cases examined. There were 158 donor cases where post-transplant malignancy was reported within six months of transplant, and another 145 (20.9%) that were reported within one year of transplant.

Of the 695 donors with more than one recipient reporting a post-transplant malignancy, the most common donor age group was 18-34 years old (42%), followed by 35-49 (26%) and 50-64 (13.7%). Only 16 of the cases examined involved donors aged 65 or older. Of note, more than two-thirds of the cases involved male deceased donors.

Members agreed that the numbers appeared low, and were dependent upon self-reporting. A member noted that numbers would probably go up as members became more familiar with the potential transmission reporting system. How many of the events captured in this report were donor derived transmissions that were not reported to the Patient Safety System? Additional analysis will be completed to compare these events to reported donor cases. Another suggestion to separate the data down to the level of pediatric versus adult was suggested. A final suggestion was made to separate out PTLD reports, because this diagnosis is not the result of a donor derived transmission.

Members noted that the current method of collecting post-transplant malignancies does not warrant a level of detail that is especially useful. These concerns will be addressed as part of the Committee's feedback and suggested changes in the OMB Forms Review process.

Patient Safety Staff are using a newly developed database that links to UNet® and will capture whenever a post-transplant malignancy form is completed for a recipient being tracked in the Patient Safety database. This will assist the Committee in following up on malignancy cases, where the 45 Day Report really does not serve any purpose.

3. Serology and NAT Updates

OPO Committee's NAT Survey Update Mr. Jeff Orlowski, Chair of the OPO Committee, presented an update on data collected during the OPO Committee's NAT survey which was conducted in collaboration with DTAC, completed March 11 through May 1, 2008 (**Exhibit K**) during the Committee's May 2009 meeting. The survey boasted a 100% completion rate, with all 58 OPOs responding to the questions. Of the 58 OPOs:

- 45 (78%) do some NAT
- 41 (71%) do some prospective NAT
- 27 (47%) do prospective NAT on all donors

The exact NAT profile/panel varied from OPO to OPO.

Twelve OPOs stated that they could not comply with a mandate to do prospective NAT or did not respond to this question. As a result, follow-up calls were made to each of these OPOs to obtain more information. Reasons offered for the inability to comply were logistics or the availability of testing in a timeframe that was workable to carry out donation. Of note, four of these twelve OPOs now believe that they could meet a mandate to complete prospective NAT testing, while eight OPOs still report that NAT testing is not feasible.

This data will be presented at ATC in May-June 2009, and the OPO Committee plans to pursue publication. A target journal has not been determined at this time.

Organ Donor Infectious Disease Testing Survey Update Ms. Taranto provided the Committee with preliminary results of the Committee's testing survey during the May 2009 meeting (**Exhibit L**). Responses to the testing survey were received from 55 of the 58 U.S. OPOs. The survey included several summary questions followed by detailed questions on the testing methods for HIV, HBsAg, HBc Total, HBc IgM, HCV, Syphilis, HTLV I/II, CMV Total, CMV IgM, EBV IgG, and EBV IgM.

Assistance was requested in identifying several test types where conflicting information regarding diagnostic or screening capabilities were reported. Multiple OPOs reported the same test kit, but there appeared to be a lack of understanding on whether these kits were approved screening or diagnostic kits. Dr. Ison will work with Ms. Taranto to identify the appropriate classification for the tests in question to allow for further analysis of the survey results. Several OPOs identified the use of a specific test that has not been available for purchase in some time. These issues will be further investigated as the data is analyzed.

Members discussed how to collect data from the outstanding three OPOs. A letter may be sent to the Executive Director of each of these OPOs with specific questions that require response. An OPO representative on the Committee noted that this information should not be difficult for an OPO to ascertain because testing types are required for tissue banking as well. The Committee is eager to collect a full data set and plans to follow it up with yearly update requests to better understand how testing needs are changing.

Review of NAT Yield Study Data Debbie Seem, RN, MPH, a Blood, Organ and other Tissue Safety Officer at the CDC, presented data on a project completed with several OPOs to determine:

- The prevalence of HIV, HBV and HCV among all potential organ donors, including high risk donors.
- The probability of undetected viremia among potential organ donors screened by serology.
- The estimated risk reduction that could be gained by NAT screening.

During the Committee's May 2009, meeting, Ms. Seem reviewed an analysis of this collected from 17 OPOs and more than 12,500 donors, from Jan 1, 2004 through June 30, 2008 (**Exhibit M**). The CDC plans to continue analysis of this data to:

- Merge remaining OPO data to the master dataset
    - Rerun analyses
- Generate confidence intervals using Monte Carlo estimation (same method as Zou, 2004)
- General population estimates (rather than blood donor) to generate organ donor incidence

The timeline for completing this additional analysis is expected to be another one to four months, as the CDC is awaiting data from one more participating OPO. An abstract will be developed for potential acceptance and presentation. Dr. Kate Ellingson, a CDC representative, noted that indeterminate results will be included in the final analysis in an effort to address false positive results. In some cases, the reporting OPOs included serology and NAT results for analysis to review the incidence of false positives more closely.

NAT Consensus Conference Update Dr. Emily Blumberg updated the Committee on the April 23, 2009 NAT Consensus Conference, held in Chicago (**Exhibit N**). During the Committee's May meeting, she presented an overview of this conference, meant to examine the role of NAT testing for HIV, HCV and HBV in organ donors.

Recommendations coming out of this consensus conference will be published shortly.

Members agreed that the high risk definition as currently written does not sufficiently flag all potential risks effectively. If NAT testing is recommended only for potential donors who meet requirements for the high risk designation, this will still not offer full protection. Conversely, employing NAT testing for

all potential donors is not necessarily appropriate due to the risk of false positive results and the number of potentially healthy organs lost.

Putting parameters around the safety of the organ pool was agreed upon as part of this Committee's role. Negative publicity is expected in incidents of major donor derived disease transmission regardless of NAT or serology testing. A member noted that the Committee must consider whether requiring NAT testing will (1) improve safety for recipients and (2) effectively evaluate potential donors rather than focusing on potential discard. A suggestion was made that the OPTN/UNOS should have a statement regarding safety, reproducibility and assessment for risk through NAT testing requirements.

Ultimately, the goal of this group was to expand the donor pool in a manner that is responsible and safe. It was noted that better serological evaluation, including the use of fourth generation assays, is available in other parts of the world, but not approved in the United States at this time, would provide a less expensive testing method that would also have potentially fewer false positives. A member questioned if there was adequate funding to generate data necessary to get fourth generation assays FDA approved for potential donors? This would allow for an improved "safety net" that will further protect potential organ recipients.

4. Policy Proposal Timeline and Discussion

Ms. Shandie Covington, Committee Liaison, updated the Committee on the current timeline for developing a public comment proposal to modify policy 4.0 and, as appropriate, related sections of policy 2.0. A new subcommittee will be developed to work on this project before sharing its draft modifications with the full committee. Volunteers for this group included Mr. Rick Hasz, Mr. Kevin Carney, and Drs. Tim Pruett, Michael Ison, and Emily Blumberg. Due to the change in Board schedule from three to two meetings a year, this proposal is expected to go to the Board in June 2010. The Subcommittee will focus on changes to diagnostic versus screening test language and section 4.7, which outlines the reporting of potential disease transmissions.

In preparation for this new subcommittee's first conference call, Ms. Covington asked that members consider the information shared in the previous presentations and read through the former Disease Transmission Advisory Group's original public comment and public comment feedback received regarding their proposed policy modifications. Suggestions were also made for this subcommittee to continue discussion regarding post-transplant testing of select groups of recipients of "high risk" organs. Many centers already have such practices in place. The subcommittee will discuss whether suggesting policy requirements in this area may be appropriate.

5. Semi-Annual Case Review

The Committee reviews information pertaining to ongoing and recently reported potential disease transmission cases during monthly case calls. This work is conducted toward building a body of evidence that will enable the OPTN to estimate the risk of unanticipated disease transmission involved in organ transplantation. During its May 2009 meeting, the Committee reviewed cases 47 through 102, reported during the latter half of 2008 in order to agree upon classification for determining the likelihood of the transmission event being donor-derived based upon the information provided by the OPO and recipient transplant centers.

Of specific interest to the committee were to bacterial transmissions. During the course of discussion, a member suggested that the current "potential" definition used to classify cases where there was active intervention with no proven infection was appropriate. Members agreed to change this classification title to "Intervention Without Documented Transmission (IWDT)."

6. Case Workflow and 45 Day Report Reviews

During the May 2009 meeting, Ms. Kimberly Taylor and Ms. Covington demonstrated a new internal database for tracking potential disease transmission cases, and spoke with the committee about streamlining the reporting and reviewing of cases. A suggestion was offered for posting 45 Day Case Follow-up Reports as survey questions in a monthly survey to allow committee members to suggest appropriate classification for determining the likelihood of the transmission event being donor derived. This idea will be piloted in the near future to allow members more opportunity to suggest classification while freeing up time during the monthly calls.

Several suggestions were made to improve upon the current 45 Day Report template (**Exhibit O**). Members do not feel they are getting enough detailed information regarding recipient health and follow-up using the form. It was unclear whether this was the result of the OPO requesting follow-up or the form not being specific enough to elicit the desired information. Several questions were suggested for addition, to include:

- Documented evidence of transmission?
    - Yes
    - No
    - Clinical Suspicion
    - Too early to know
- Date of last evaluation
- Were additional studies that the DTAC recommended completed or scheduled for the recipient?
- List interventions specific to recipient for potential transmission.

Because Patient Safety Staff are already contacting transplant centers to confirm OPO contact to inform of potential transmission and follow up on patient status, testing results and treatment/prophylaxis, a member suggested that it may be more appropriate for staff to complete the 45 Day Report instead of the OPOs. This issue will be discussed internally at UNOS to determine if there are enough staff resources to manage this additional task.

The Committee suggested the creation of a summary page that outlines pertinent information on the donor and all recipients that would accompany the 45 Day report for Committee review and also to assist in a quick reference for archiving purposes. Patient Safety Staff is already working to see if such a summary document could be automatically generated by the internal database.

It was noted that the Committee must be mindful of its purview. It is acceptable to suggest testing methods in order to confirm or rule out donor derived transmission. It must also be recognized that insurance may not pay for some of this testing, and therefore it may not always be carried out as requested. It is not appropriate for this group to suggest specific treatment unless a center specifically asks for guidance. A more appropriate approach would be to encourage centers to involve local transplant infectious disease or oncology experts.

On a related note, the idea of designating a Patient Safety Contact at each OPO and transplant center was discussed as a more efficient way to communicate information critical to potential transmission cases. OPOs and staff members often have a great deal of difficulty finding the appropriate contact to share information on a reported case and follow-up on recipients effectively. In some events, if information is not communicated swiftly, patient safety is at risk without treatment. Having a designated contact that is

expected to communicate this information to the appropriate physician would alleviate much of this concern. This idea will be investigated, as bylaws would have to be modified to require such a position at member organizations.

There was lengthy discussion regarding how to control the number of emails going out regarding cases. Any new cases or critical updates will be posted in real time. Patient Safety Staff will make an effort to hold routine updates until approximately 3pm ET.

Members also reviewed and discussed the draft letters to close cases deemed as not a transmission or indeterminate (**Exhibit P**). Current plans approved by UNOS Legal Counsel involved sending these letters only to the Host OPO, who would in turn be responsible for notifying recipient transplant centers. Committee members disagreed with this idea, and felt that transplant centers should receive a copy as well to ensure that information is properly distributed. These concerns will be taken back to Legal Counsel for further consideration before any letter distribution is initiated.

7. <u>OMB Donor, Candidate and Recipient Forms Review Subcommittee Update</u>

The OMB Forms Review Subcommittee convened by teleconference on January 21, February 11, and March 13, 2009, to review current Deceased Donor Registration (DDR), Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR), Transplant Recipient Follow-Up (TRF), Living Donor Follow-Up, and Post-Transplant Malignancy (PTM) forms used to follow organ donors, transplant candidates and transplant recipients. Prior to expiration in November 2010, any modifications must be approved by HRSA and the OMB and programmed for implementation. All OPTN/UNOS Committees were asked to review the forms and provide any feedback they may have by late spring 2009. This subcommittee was asked to focus its expertise on serology and malignancy data.

Over the course of three teleconferences, Subcommittee members reviewed all of the various forms and provided their opinions on what fields should be removed, edited or added. All modifications included rationale for consideration by the Policy Oversight Committee (POC), Ad Hoc Data Management Group (AHDMG) and Board of Directors. Once the review process was completed, all suggestions were sent to the full DTAC for consideration.

The Committee reviewed the various suggestions made by the Forms Review Subcommittee during its March 19 teleconference and offered some minor revisions to subcommittee's suggestions.

A great deal of discussion centered around a question on the DDR meant to capture data on infections in donor. The current question is:

> **Clinical infection?** Yes, No, or Unknown.
> **Source?** blood, lung, urine, other. (Choose as many as appropriate)

The Subcommittee suggested adding:

> **Confirmed by culture?** Yes or No.
> If yes, **identify organism**. (text box will be provided)

Members questioned who would be completing these forms. Concerns were raised that someone other than a clinician may not be able to respond to this modified question, as it may not be specifically referenced in the donor chart or on DonorNet. The data entered may not be totally reliable if the data entry person does not have enough detail in the chart or the understanding of this information to complete

the form appropriately. There was also a question of whether the cultures to be referenced were hospital drawn or OPO drawn cultures.

It was noted that all suggested changes to the DDR will also be reviewed by the OPO Committee prior to POC. A member noted that he did not believe the OPO Committee would be comfortable with this addition to the form.

Dr. Ison recognized that the desire for this information is valid, but if poor quality information is going to be entered it may not be wise to add the additional detail to this question. An OPO representative noted that currently, a positive culture would spur a positive response to this DDR question. It may not always be available pre-recovery, and adding a field to denote this would call for a full re-design of the form.

While all members agreed that they wanted to include this question and the related detail, disagreement remained regarding what the quality of this data would be. A separate call with OPO Committee representation was suggested to work through this issue. Members agreed to this idea and continued through their review of the documentation.

After review and discussion of all revisions, members voted unanimously in support of all changes recommended by the OMB Forms Review Subcommittee (**Exhibit Q**), to include minor edits as suggested, with the exception of the clinical infection question (6 in favor, 0 opposed, 0 abstentions).

Issues related to the clinical infection in the donor will be discussed with the OPO Committee at a later date.

Once complete, UNOS Research staff will forward all recommendations on to the AHDMG and POC for review before going to the Board of Directors.

8. Newsletter Subcommittee

The Committee's newest subcommittee, the Newsletter Subcommittee, was introduced during the May 2009 meeting. The group, chaired by Dr. Lewis Teperman, will be producing a bi-annual electronic newsletter that will be sent to OPTN/UNOS members, with additional "dispatches" available on an as needed basis to address time sensitive critical events. Communications staff will assist Patient Safety staff in the production and distribution of this document, and the goal of keeping to document brief but informative to encourage readers to review the full document.

The newsletter will report on general concepts and trends that the Committee is recognizing as it reviews cases (i.e. careful cleaning and inspection of kidneys at the donor recovery hospital to prevent RCC transmissions, prevention and early identification of donor derived bacterial transmissions, recommended testing for specific scenarios like molecular fingerprinting used for malignancy transmission identifications, etc). The subcommittee recognizes the importance of sharing information without damaging the confidential medical peer review process.

9. Review of Policies and Bylaws Issued for Public Comment

The Committee reviewed the four proposals released for public comment in October 10, 2008, during its December 18, 2008, conference call.

1. Proposal to allow candidates who need a pancreas for technical reasons as part of a multiple organ transplant to be listed on the pancreas waiting list. Policies Affected: Policy 3.2.7 (Pancreas Waiting

List Criteria) and Policy 3.2.9 (Combined Kidney-Pancreas Waiting List Criteria) *Pancreas Transplantation Committee*

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

2. Proposal to clarify islet allocation protocol. Policy Affected: Policy 3.8.1.6 (Islet Allocation Protocol) *Pancreas Transplantation Committee*

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

3. Proposal to increase the safety of allocations to candidates who do not appear on the match run. Policies affected: Policy 3.1 (Definitions), Policy 3.2.4 (Match System Access), and Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates) *Membership and Professional Standards Committee*

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

4. Policy Affected: Policy 2.0 (Minimum Procurement Standards for an Organ Procurement Organization Proposal to Clarify, Reorganize and Update Policy 2.0 - Minimum Procurement Standards for an Organ Procurement Organization) *Organ Procurement Organization (OPO) Committee*

   - Members raised concerns that such potential policy creates minimum standards for which OPOs are held accountable that may be unrealistic. Members disagreed with proposed changes to require sputum cultures for all donors. They argued that this information is not pertinent for all organs and is a potential waste of resources if considered as a minimum requirement for every donor case. The Committee suggested that the OPO Committee work with both the DTAC and the Thoracic Committee to determine appropriate cultures necessary for lung donors only.

     Additional concerns were raised regarding the term "as required." Members found this language confusing for the reader. It was recognized that all OPOs have standard protocols that are followed for donor management unless a specific drug or test is requested by a prospective recipient center. Members believed that the language, as written, is too vague to ensure compliance. The Committee suggested that the OPO Committee re-word this section of policy to reduce the current ambiguity.

     After consideration and discussion, members voted in favor of the proposal, but requested that the OPO Committee consider the feedback provided above (7 in favor, 0 opposed, 0 abstentions).

The Committee reviewed the eight proposals released for public comment on February 6, 2009, and provided the following feedback during its March 19, 2009 conference call.

1. Proposed listing requirements for simultaneous liver-kidney transplant candidates (Policy proposed: 3.5.10 – Simultaneous Liver-Kidney Transplantation) *Kidney Transplantation Committee and Liver and Intestinal Organ Transplantation Committee*

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

2. Proposal to create regional distribution of livers for Status 1 liver candidates (Policy affected: 3.6 - Allocation of Livers) *Liver and Intestinal Organ Transplantation Committee*

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

3. Proposal to create regional distribution of livers for MELD/PELD candidates (Policy affected: 3.6 - Allocation of Livers) *Liver and Intestinal Organ Transplantation Committee*

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

4. Proposal to standardize MELD/PELD exception criteria and scores (Policy affected: 3.6.4.5 – Liver Candidates with Exceptional Scores) *Liver and Intestinal Organ Transplantation Committee*

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

5. Proposal to add the factors "current bilirubin" and "change in bilirubin" to the lung allocation score (LAS) (Policy affected: 3.7.6.1 (Candidates Age 12 and Older) *Thoracic Organ Transplantation Committee*

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

6. Proposal to modify the high risk donor policy to protect the confidential health information of potential living donors (Policy affected: 4.1.1 - Communication of Donor History) *Living Donor Committee*

   - After review and brief discussion, members voted unanimously in favor of the proposal, (6 in favor, 0 opposed, 0 abstentions)

     In light of the upcoming creation of a separate section of policy to specifically address living donation, the committee would like to offer its guidance to the Living Donor Committee in determining the types of testing appropriate for potential living donors and follow-up of living donors, as well as the timing for when these tests should be completed.

7. Proposal to change the OPTN/UNOS Bylaws to clarify the process for reporting changes in key personnel (Bylaws affected: Appendix B, Section II,E (Key Personnel); Appendix B, Attachment 1, Section III (Changes in Key Personnel) *Membership and Professional Standards Committee*

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

8. Proposal to clarify, reorganize and update OPTN policies on OPO and transplant center packaging, labeling and shipping practices (Policy affected: 5.0 – Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials) *Organ Procurement Organization (OPO) Committee*

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

10. <u>Review of Bacterial Transmissions</u>

Dr. Ison highlighted a number of bacterial transmissions reported through the Patient Safety System in 2008 during the May 2009 meeting. He emphasized the critical importance of OPOs sharing all positive culture results with transplant centers considering organ offers and accepting organs. The Committee also discussed requiring the number and length of hospital stays for all potential bacterial transmission cases

and copies of all culture results along with the initial report. A member also suggested the difficulty in reviewing and familiarizing OPO staff with electronic records. It can be challenging to find all pertinent information on a donor when you are not familiar with a specific records system. These and other recommendations are an expected newsletter article.

11. TB Case Standardization

Dr. Elizabeth Ortiz-Rios, HRSA representative to the Committee, provided members with an overview of a project currently underway by a masters degree student currently interning at HRSA, Ms. Lenise Chege. Ms. Chege reviewed 13 TB cases reported to the Patient Safety System from 2006 through early 2009 in order to develop a standard protocol for data collection, recipient work up and potential intervention recommendations in such cases. This information will be helpful to Patient Safety Staff when speaking with recipient centers who ask for suggestions on testing for potentially infected recipients. The project is still underway at this time, and the final product will be shared with the Committee for consideration at a later date.

12. DTAC Paper Review

Dr. Ison reported that a manuscript summarizing donor-derived disease transmissions since the creation of the DTAC in 2005 was accepted for publication in the ***American Journal of Transplantation***.

13. CDC Case Follow-up

Dr. William Bower, a representative of the CDC's Office of Blood, Organ and other Tissue Safety on the Committee, requested a more prompt efficient sharing of information between Patient Safety and CDC staff, including transplant center contact information during the May 2009, meeting. The CDC would like to develop a protocol or strategy for their involvement in cases reported to the Patient Safety System. After brief discussion, a recommendation was made to hold a separate meeting to discuss the CDC's request with HRSA representation at a later date.

14. Review of Member Appointment Terms

Committee term dates were finalized to ensure that half of the committee would roll off in June 2010, and new members would begin two year terms. All members were encouraged to review the roster included in their meeting materials. During the May 2009, meeting. Dr. Ison thanked Mr. Jim Cutler for his commitment and service to the Committee, and recognized his service with a certificate.

# AD HOC DISEASE TRANSMISSION ADVISORY COMMITTEE

| NAME | COMMITTEE POSITION | 11/20/08 teleconference | 12/01/08 teleconference | 12/18/08 teleconference | 1/15/09 teleconference | 2/19/09 teleconference | 3/19/09 teleconference | 4/3/09 teleconference | 4/16/09 teleconference | 5/6/09 meeting in Chicago |
|---|---|---|---|---|---|---|---|---|---|---|
| Michael Ison, MD, MS | Chair | X | X | X | X | | X | X | X | X |
| Michael Nalesnik, MD | Vice Chair | | X | X | X | X | X | X | X | X |
| Emily Blumberg, MD | At Large | X | X | X | X | X | | X | X | X |
| Kevin Carney, RN, CCTC | At Large | | | | | | | X | | X |
| James Cutler, CPTC | At Large | X | | X | X | X | | | X | X |
| J. Michael DiMaio, MD | At Large | | | | | | X | X | | X |
| Michael Green, MD, MPH | At Large | X | | | | | X | | | X |
| Richard Hasz Jr., MFS | At Large | X | | | | X | X | | X | X |
| Bernard Kubak, MD, PhD | At Large | | X | X | X | X | X | X | X | X |
| Lewis Teperman, MD | At Large | | X | | | | | X | | X |
| Brahm Vasudev, MD | At Large | X | | X | X | | | | X | X |
| Timothy Pruett, MD | At Large | | X | | | X | | X | | X |
| Amy Shorin-Silverstein, JD | BOD Liaison | | | | | | | | | phone |
| Matthew Kuehnert, MD | CDC | | | X | | X | | | X | phone |
| Richard Durbin, MBA | Ex Officio | X | X | | | | | | | |
| Elizabeth Ortiz-Rios, MD, MPH | Ex Officio | | X | X | X | | X | | | phone |
| Christopher McLaughlin | Ex Officio | X | | | | | | | | phone |
| | | | | | | | | | | |
| Shandie Covington | Committee Liaison | | X | X | X | X | X | X | X | X |
| Kimberly Taylor, RN | Support Staff | X | X | X | X | X | X | X | X | X |
| Kimberly Parker | Support Staff | | | | | | X | X | X | phone |
| Sarah Taranto | Support Staff | X | X | X | X | X | X | X | X | X |
| Mary D Ellison, PhD, MSHA | Support Staff | | | | | | | | | X |
| Lin McGaw, RN, MEd | Support Staff | X | | X | X | | | | X | |
| Stacey Burson | Support Staff | | | | | X | | X | X | phone |
| Bob Metzger, MD | Support Staff | | | | | | | X | | X |
| William Bower, MD | CDC | | X | | X | X | X | X | | X |
| Debbie Seem, RN, MPH | CDC | X | X | X | | | X | X | X | phone |
| Kate Ellingson, PhD | CDC (guest) | | | | | | | | | phone |
| Bernie Kozlovsky, MD, MS | Ex Officio | | | | | X | X | X | | X |
| James Bowman, MD | Ex Officio | | | | | | X | X | X | |
| Robert Walsh, | Ex Officio | | | | | | | | | phone |
| Daniel Kaul, MD | guest speaker | | | | | | | | | phone |
| Jeff Orlowski, MS, CPTC | guest speaker | | | | | | | | | phone |