DTAC Action Item #1

Proposed Clarification to Policy 2.2.3.2

- Meant to clarify that HIV antibody screening should be completed for all potential deceased donors using commonly accessible antibody testing of donor serum in order to meet current policy requirements.

- While NAT may be completed in addition to antibody screening, it is not by itself an acceptable alternative to meet this policy requirement.

OPTN
Additional Data Collection

- This proposal creates no additional data collection requirements for OPOs.
- HIV screening information is already collected on the Deceased Donor Registration (DDR) form. HIV positive donor organs may not be used for transplant per the Final Rule.
Housekeeping Change

- This proposal is a housekeeping change, meant to clarify current deceased donor HIV screening requirements.

- It did not go out for public comment.
Proposed Modification

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.
DTAC Action Item #2

Proposed Guidance for HTLV-1 Screening and Confirmation in Potential Donors and Reporting Potential HTLV-1 Infection.
On Oct 23, 2009, the OPTN/UNOS Executive Committee eliminated the requirement for pre-transplant deceased donor HTLV-1/2 testing, effective November 23, 2009.

The basis for this decision included:

- considerable organ wastage due to false positive results using screening tests,
- the very low prevalence of HTLV-1 in the U.S., and
- the impending lack of availability of an FDA licensed HTLV-1 screening test that could practically be used in most OPO labs.
OPTN removed requirement for pre-tx donor screening, but some OPOs may elect to continue routine donor screening, to screen potential living donors, or to perform targeted screening on donors perceived to be at higher risk of HTLV-1 infection.

While the American Association of Tissue Banks (AATB) and the FDA do not require testing of any but leucocyte rich tissues, there may be situations where testing of other tissue reveals donor infection.
Guidance Document

DTAC was charged with creating a guidance document to assist the transplant community with ongoing testing issues and questions related to HTLV-1 in the organ transplant community.
Document Development

- Developed with review of the AJT article written by the ad hoc HTLV Subcommittee that developed the HTLV screening requirement proposal:

Guidance Document Includes:

- Circumstances in which HTLV donor screening may be performed
- Symptom driven testing in recipients
- Informing recipients of positive HTLV donor results
- Management and monitoring of patients receiving organs or vessels from confirmed screen positive donors
- Reporting of recipients found to be HTLV-1 positive
- What specific test types are appropriate for HTLV-1/2 screening, monitoring and confirmation?
*** 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

OPTN
DTAC Action Item #3

Proposed Guidance for Reporting Potential Donor-Derived Disease Transmission Events (PDDTE).
On November 8, 2010, the OPTN/UNOS Board of Directors approved a re-write of OPTN Policies 2.0 and 4.0. These policy changes were implemented on January 10, 2011.

Part of this rewrite covered the communication and reporting of all suspected or confirmed donor-derived disease and malignancy transmissions in organ recipients.
To assist members in better understanding the changes in this area of policy, DTAC was charged with creating a guidance document to outline the types of events that should be reported as well as the timeline and sequence of events for successful reporting to promote patient safety.
Circumstances Where Reporting a PDDTE is Required

In general, there are two levels of handling of potential donor-derived disease transmission event (PDDTE):

- Communication of the finding between the Host OPO and recipient TX Center Patient Safety Contact; or

- Communication of the finding between the Host OPO and recipient TX Center Patient Safety Contact and reporting of the case through the Improving Patient Safety Portal in Secure Enterprise™.

OPTN
To Report or Not to Report?

In determining whether to report the event to the Improving Patient Safety portal (as required by OPTN Policy 4.5 (Post-Transplant Reporting of Potential Transmission of Disease or Medical Conditions, Including Malignancies), there needs:

- Evidence of infection or disease in both the donor and recipient; or
- Substantive concern of potential donor-origin of disease in a recipient; or
- Evidence of similar disease in multiple recipients receiving organs from the same donor.

OPTN
Helpful information regarding disease and malignancy reporting is included.

In any instance, if you are unsure whether a specific situation should be reported as a PDDTE, it is recommended that you report in order to promote patient safety.
*** 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
Potential Disease Transmission Cases Reported to DTAC

- 2005: 7 cases
- 2006: 60 cases
- 2007: 97 cases
- 2008: 102 cases
- 2009: 152 cases
- 2010: 157 cases
Ad Hoc Disease Transmission Advisory Committee: A Report to the OPTN/UNOS Board

Emily A. Blumberg, MD
Chair, OPTN/UNOS DTAC

Shandie Covington
UNOS Staff Liaison, DTAC

June 28-29, 2011
Richmond, Virginia
DTAC Action Items

- Proposed Clarification to Policy 2.2.3.2
- Proposed Guidance for HTLV-1 Screening and Confirmation in Potential Donors and Reporting Potential HTLV-1 Infection.
- Proposed Guidance for Reporting Potential Donor-Derived Disease Transmission Events (PDDTE).
DTAC: Board Goals

1. Recommend modifications of OPTN policies 2.0 & 4.0 to improve screening and diagnostic testing for donor disease transmission.

2. To always provide the most current info on frequently transmitted diseases, remove the list of such diseases from OPTN Policy and develop a guidance doc that can be updated more frequently/easily.

3. Produce a DTAC newsletter twice a year for OPTN members to share information regarding disease transmission concepts.
4. Conduct a follow-up survey of all OPOs regarding current screening practices to determine how these practices have changed based on changing test kit availability and the new CDC Guidelines to be released...

DTAC awaits the released of the new CDC/US PHS Guidelines, but plans to get this follow-up to the 2008 survey in 2011-12.

5. Review potential donor-derived transmissions since donor HTLV screening requirement was eliminated in November 2009, and develop a guidance document to help OPOs and TX Centers that continue to test.
6. Publish disease transmission data in journals, abstracts and present at professional meetings to increase community awareness of disease transmission.
   - Ongoing efforts include ATC, NATCO, AOPO, IDSA, UNOS Primer and recent AJT malignancy publication

7. Guidance documents on bacterial, TB, and fungal transmissions to promote practices that reduce disease transmission.
   - Committee developing documents based upon what it is learning from review of aggregate case data. Encephalitic donor guidance is currently being developed.
Other Projects and Issues

- Participating in the **Optimal Testing of Live Donors to Prevent Transmission of Infectious Diseases** consensus conference in July. Assist the Living Donor Committee in developing potential living donor screening policy language.

- Addressing research and off label test use in donors seen in several cases potential donor-derived disease transmission events.

- Continuing to grow the patient safety contact list and request programming to increase accessibility.

- Active presence in ACBSA meeting as it gains organ tx representation and considers global issues regarding biovigilance.
Potential Donor-Derived Disease Transmission Case Review

What have we learned in the last 6 years?
DTAC Cases Reported 2006-2010

Year | Cases
--- | ---
2006 | 60
2007 | 97
2008 | 102
2009 | 152
2010 | 157
## Summary of Reported Cases: 2005 - 2010

<table>
<thead>
<tr>
<th>Disease Types</th>
<th># of Donor Reports</th>
<th># of Recipients w/ Confirmed Tx</th>
<th># of DDD-Attributable Recipients Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Malignancies</td>
<td>170</td>
<td>44</td>
<td>15</td>
</tr>
<tr>
<td>Viruses</td>
<td>126</td>
<td>27</td>
<td>11</td>
</tr>
<tr>
<td>Bacteria</td>
<td>84</td>
<td>31</td>
<td>9</td>
</tr>
<tr>
<td>Fungi</td>
<td>49</td>
<td>27</td>
<td>10</td>
</tr>
<tr>
<td>Mycobacteria</td>
<td>36</td>
<td>9</td>
<td>2</td>
</tr>
<tr>
<td>Parasites</td>
<td>30</td>
<td>18</td>
<td>7</td>
</tr>
<tr>
<td>Other Diseases</td>
<td>28</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>523</strong></td>
<td><strong>156</strong></td>
<td><strong>54</strong></td>
</tr>
</tbody>
</table>

Data includes cases classified as possible, probable or proven from 2005-2007 as published in AJT, and all cases from 2008-2010.

OPTN
## Malignancy Reports: 2005-2010

<table>
<thead>
<tr>
<th>Malignancy</th>
<th># of Donor Reports</th>
<th># of Recipients with Confirmed Transmission</th>
<th># of DDD-Attributable Recipient Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal Cell Carcinoma</td>
<td>79</td>
<td>9</td>
<td>1</td>
</tr>
<tr>
<td>Lung Cancer</td>
<td>14</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Thyroid Carcinoma</td>
<td>10</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Brain Cancer</td>
<td>8</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Hematologic Malignancy</td>
<td>7</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Lymphoma</td>
<td>6</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>Liver Cancer</td>
<td>6</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Melanoma</td>
<td>6</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Prostate Cancer</td>
<td>5</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Pancreas Cancer</td>
<td>3</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>Neuroendocrine</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Ovarian Carcinoma</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Breast Cancer</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Colon</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Kaposi’s Sarcoma</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other **</td>
<td>16</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td><strong>Malignancy Total</strong></td>
<td><strong>170</strong></td>
<td><strong>44</strong></td>
<td><strong>15</strong></td>
</tr>
</tbody>
</table>
## Transmissions and Deaths

<table>
<thead>
<tr>
<th></th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Reports</td>
<td>152*</td>
<td>157*</td>
</tr>
<tr>
<td>Number of deceased donors</td>
<td>8022</td>
<td>7943</td>
</tr>
<tr>
<td>Proven/Probable Transmissions (%) reports</td>
<td>33 (21.7%)</td>
<td>37 (24%)</td>
</tr>
<tr>
<td>Proven/Probable Transmissions as Percentage Deceased Donors</td>
<td>0.4%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Deaths from Proven/Probable Transmissions</td>
<td>13</td>
<td>13</td>
</tr>
</tbody>
</table>

*Some cases were reported on donors recovered in earlier years, and additional cases will be reported in the future on donors recovered during this time period.
2011 Reports Through May

- 67 reports reviewed by DTAC Jan-May 2011
  - 22 bacterial reports (1 probable)
  - 13 fungal reports (1 probable/1 proven)
  - 12 viral reports (3 proven)
  - 15 malignancy reports (2 proven)
  - 5 “other” reports (parasites, FUO that was later excluded, etc.) (1 proven)
DTAG/DTAC: The First Six Years – Impact on Policy

**Successes**
- Awareness of disease transmission
- Guidance/Policy development
- Key observations
  - Donor pool expansion
  - Testing issues
  - Bacterial infections
  - Encephalitis
  - Malignancy observations

**Challenges**
- Reporting
  - Uneven participation
  - Live donation
- Optimal testing for certain pathogens
- Differentiation of malignancy and infection issues
- Communication

OPTN
Communication Gaps

Delays and errors in communication can have a significant impact on recipient morbidity and mortality

- MMWR, 59:1642, 2010
- MMWR, 60: 297, 2011

“Communication Gaps Associated with Donor Derived Infections”
presented at ATC 2011 and received a great deal of press!
Major Areas Identified

- Failure to recognize a potential PDDTE in donor and/or recipient
- TXcenter delayed contacting the OPO with a suspected PDDTE
- OPO delay in contacting DTAC or transplant centers
- Failure of labs to relay donor results to the OPO and/or transplant center
- Test results communicated by OPO to transplant centers were incomplete
- Clerical errors
Percent of Deceased Donors Recovered 2008-2009 Reported to DTAC by Region
Percent of Deceased Donors Recovered
2008-2009 Reported to DTAC by DSA

Percent of Recovered Deceased Donors with a Case Reported vs. DSA of Donor Recovery

OPTN

UNOS DONATE LIFE
# DTAC Members (2010-2011)

<table>
<thead>
<tr>
<th>Chair</th>
<th>Vice Chair</th>
<th>TID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Emily Blumberg</td>
<td>Dr. Michael Green</td>
<td>(Peds TID)</td>
</tr>
<tr>
<td>Dr. Daniel Kaul</td>
<td>Ms. Alison Smith</td>
<td>(OPO)</td>
</tr>
<tr>
<td>Dr. Afshin Ehsan (Thoracic TX Surgeon)</td>
<td>Dr. Michael Nalesnik (TX Pathologist)</td>
<td></td>
</tr>
<tr>
<td>Dr. Tom Gross (TX Oncology)</td>
<td>Dr. Dan Lebovitz (Ped Critical Care, OPO)</td>
<td></td>
</tr>
<tr>
<td>Dr. George Lyon (TID)</td>
<td>Dr. Bernie Kubak (TID)</td>
<td></td>
</tr>
<tr>
<td>Dr. Betsy Tuttle-Newhall (Abd TX Surgeon)</td>
<td>Dr. Brahm Vasudev (TX Physician)</td>
<td></td>
</tr>
<tr>
<td>Dr. Tim Pruett (Abd TX Surgeon)</td>
<td>Dr. Rachel Miller (TID)</td>
<td></td>
</tr>
<tr>
<td>Ms. Carrie Comellas (TX Coordinator)</td>
<td>Mr. Barry Friedman (TX Administrator)</td>
<td></td>
</tr>
<tr>
<td>Ms. Linda Weiss (OPO laboratory)</td>
<td>Dr. Jim Bowman (Ex Officio, HRSA)</td>
<td></td>
</tr>
<tr>
<td>Dr. Michael Ison (Ex Officio, TID)</td>
<td>Bernie Kozlovsky (Ex Officio, HRSA)</td>
<td></td>
</tr>
</tbody>
</table>

* CDC removed itself from DTAC Ex Officio representation on 8/31/10
Questions?

Emily Blumberg, MD
- Univ of PA Med Center
- 215-662-7066
- blumbere@mail.med.upenn.edu

Shandie Covington
- UNOS
- 804-782-4929
- shandie.covington@unos.org

Special Thanks: Sarah Taranto, Kimberly Taylor, Kimberly Parker as well as the entire Committee!

OPTN
Thanks!

Chair: Emily Blumberg, MD
Vice Chair: Michael Green, MD

OPTN