Guidance on Identifying Risk Factors for West Nile Virus (WNV) in Potential Living Donors

Ad Hoc Disease Transmission Advisory Committee

Dr. Michael Green, MD, MPH, Chair
June 24-25, 2013
Background

OPTN living kidney donor medical evaluation policy implemented in February 2013

- Requires WNV testing for potential kidneys donors from endemic areas
- Confusion in the community regarding specifically who should be tested
Living Donor Committee requested that the DTAC develop guidance to:

- Define “endemic areas” for exposure and infection
- Discuss testing options
Document Development

The DTAC formed a Work Group to develop this guidance:

- AST Infectious Disease Community of Practice representation
  - Reviewed discussion from 2010 Donor Derived Consensus Conference for Solid Organ Transplantation on WNV

- Reviewed FDA and CDC guidance on this topic for the blood community
Summary of Guidance

The document includes:

- Epidemiology and pathophysiology of WNV
- FDA approved testing options
- DTAC experience on potential transmissions to date
- Risk factors (geographic and seasonal)
- Who and when to test
- What to do with a positive donor test or history of WNV
- Exposure management
Summary of Guidance

- Most WNV infections are asymptomatic
  - Clinical evaluation will not effectively identify all infection
  - Lab testing recommended during periods of human WNV activity where donor lives, works, or travels

- FDA approved screening = NAT

- Initiation of testing based on local human WNV activity informed by local blood bank results
  - May allow centers to test only during periods when human disease is present
  - May reduce false positives and testing costs

- Seasonal testing is an alternative, but not as cost effective
If approved...

- Guidance document will be posted on the OPTN website as a professional resource

- Will be highlighted in UNOS Update and DTAC News e-newsletter
RESOLVED, that the updated guidance document “Guidance for Identifying Risk Factors for West Nile Virus (WNV) in Potential Living Donors,” set forth in Exhibit A to the DTAC’s report to the Board, is hereby approved, effective June 25, 2013.
Questions?

Thank you.
Enhancements to the Disease Transmission Reporting Section of the Improving Patient Safety Portal in UNetSM

Ad Hoc Disease Transmission Advisory Committee

Dr. Michael Green, MD, MPH, Chair
June 24-25, 2013
Current Reporting Relies on Open Text Field

- Little consistency in reporting
  - Some sparse, some very lengthy but not including the information DTAC needs to begin review of a potential transmission

- Inefficient for members
  - Time consuming to draft a narrative
  - Greater opportunity for errors or miscommunication

- Inefficient for staff
  - Can be difficult to glean the details needed by the DTAC without contacting the reporter for more information
An efficient avenue for members to report cases of malignancy and infectious diseases.

**Event Information**

- **Reporting event for:**
  - Donor
  - Recipient

- **Reporting Institution:**

- **Detected by:**

- **Date occurred:**

- **Medical Condition/Disease:**

- **Date detected:**

- **Description:**

**Contact Information**

Who at your institution should UNOS contact about this case?

First name: *

Last name: *
Proposed Modifications

- Prompts reporter for standard information needed in most potential transmission event reviews
- Incorporates many drop downs and pick lists for diseases and related testing
- Will allow for review of reported data in a more automated fashion within the Improving Patient Safety portal

Modifications expected to streamline reporting process for submitter and staff managing case review!
### Figure 6 Expanded view Donor PDDTE

**Event Information**

- **Reporting event for:** Donor (living or deceased)
- **Donor ID:** Z00045
- **Reporting Institution:** AZCB-Donor Network of Arizona-Independent OPO (Member)
- **Have all of the recipient centers been notified at this time?** Yes
- **Detected by:** Jane Smith

**Infection/Malignancy/Other Medical Condition (choose all of the appropriate conditions being reported):**

- **Infection:**
  - Encephalitis
- **Malignancy:**
  - Basal Cell
- **Other Medical Condition:**
  - Hemochromatosis

**Specify Type**

- **Infection:** Fungal
- **Malignancy:** ABCD
- **Other Medical Condition:** ABCD

**Date Detected**

- **Infection:** 06/07/2011
- **Malignancy:** 06/07/2011
- **Other Medical Condition:** 06/07/2012

**Please attach any relevant documents, including lab or diagnostic testing results.**

*Attachments*

Maximum file size 50mb

**At this time, diagnosis is:**

- **Confirmed**
- **Suspected**

**Was an assay or other test used to identify organism disease?** Yes

**If yes, list assay/test type, results and date identified (please upload copy of results when available):**

- **Assay/Test Type:**
- **Results:**
- **Date:**
At this time, diagnosis is:  
- Confirmed
- Suspected

Was an assay or other test used to identify organism disease?  
- YES  
- NO

If yes, list assay/test type, results and date identified (please upload copy of results when available):

<table>
<thead>
<tr>
<th>Assay/Test Type:</th>
<th>Results:</th>
<th>Date:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Was the donor blood sample obtained pre or post transfusion?  
- Pre  
- Post  
- Not available  
- Unknown

What donor specimens remain for further testing? (please include type and amount):  

Was tissue recovered from this donor?  
- YES  
- NO

Was an autopsy completed on this donor? (please upload copy of autopsy report if available):  
- YES  
- NO

Have local/state Public Health authorities been contacted regarding this event  
(if appropriate for nationally notifiable infectious diseases as defined by the US Public Health Service)?  
- YES  
- NO

If yes, please list the name and phone number of your contact:

- Name:  
- Phone:  
- Phone:  

Enter narrative description of this event:*  

Enter a detailed description of the event here:  

Contact Information

Who is the patient safety contact at your institution for this event?

- First name:*  
- Last name:*  

Phone contact (Enter at least one):  
- Office:  
- Mobile:  
- Pager/beeper:  
- Other:  

Email:*  

Other contact info:
Related Programming

- **Project Size = Large Effort**
  - 1570 hours estimated / $89,219 in cost
  - Bulk of time will be IT-related: 1430 hours
    - Split between programming, testing, and education (related to updating help documentation, system notice, etc)

- **Part 3 of 3 updates to the Improving Patient Safety Portal**
  - Operations & Safety updates for Patient Safety Situation reporting = very large effort (2580 hours / $146,848)
  - Living Donor Committee updates to Living Donor Adverse Event reporting = medium effort (730 hours / $43,155)
Expected Benefits

- For members submitting PDDTE reports
  - Easier to know WHAT to report rather than developing a narrative
  - Clicking various options MORE TIME EFFICIENT than drafting a narrative

- For UNOS staff managing cases
  - Information easier to process and prepare for DTAC review
  - Receiving the RIGHT information on the front end allows for expedited handling and communication to other recipient centers as needed

Overall, these modifications will allow for a more efficient process all users and enhanced patient safety!
RESOLVED, that proposed enhancements to the Improving Patient Safety Portal for reporting potential donor-derived disease transmission events be programmed and implemented, effective pending programming and notice to the OPTN membership.

*Page 18 of Board book
Questions?

Thank you.
Factors to Consider During Living Donor Evaluation

- Has human infection with WNV virus been recognized locally this WNV season?

- Has the donor travelled to an area with human WNV activity this WNV season?

- Has the donor ever been diagnosed with WNV fever or WNV neuroinvasive disease?

- Has the donor had an undifferentiated febrile illness within the current WNV season?

- Has the donor had significant mosquito exposure this WNV season?