

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 kidney donors from endemic areas
- Confusion in the community regarding specifically who should be tested

Background

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

Resolution 2

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.

**Page 5 of Board book*

Questions?

Thank you.

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

*Ad Hoc Disease Transmission
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*Dr. Michael Green, MD, MPH, Chair
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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

Disease Transmission event - Windows Internet Explorer

https://portal.unos.org/PatientSafety/ViewDiseaseTransmission.aspx?TRKR=oa%2bYWXqFMITwHkgTMPI

File Edit View Favorites Tools Help

Event Information

Reporting event for:* Donor Recipient

Reporting Institution:*

Detected by:*

Date occurred:* MM/DD/YYYY

Medical Condition/Disease:*

Date detected:* MM/DD/YYYY

Add

Description:*

Contact Information

Who at your institution should UNOS contact about this case?

First name:*

Last name:*

SEARCH FOR AN EVENT

LEGAL NOTICE

Reporting a situation or circumstance on this site does not imply or provide any policy, regulatory, or legal protections or immunity. It is expected that the information reported will provide data analysis; enhance patient safety; and improve the organ donation and transplantation system.

Free-form text field

Done Local intranet 100%

start 14 Micros... 2 Micros... 2 Micros... Secure Ent... Disease Tr... 2013_06_D... 2:47 PM

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) Recipient

Donor ID:

Reporting Institution:

Have all of the recipient centers been notified at this time? YES NO

Detected by:

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

Infection Malignancy Other Medical Condition

Infection:	Specify Type:	Date Detected:	
<input type="text" value="Encephalitis"/>	<input type="text" value="Fungal"/>	<input type="text" value="06/07/2011"/>	<input type="button" value="EDIT"/>
Infection Encephalitis	Specify Type Fungal	Date Detected 06/07/2011	<input type="button" value="Delete"/> <input type="button" value="Add"/>
<input type="text" value="Basal Cell"/>	<input type="text" value="ABCD"/>	<input type="text" value="06/07/2011"/>	<input type="button" value="EDIT"/>
Malignancy Basal Cell	Specify Type ABCD	Date Detected 06/07/2011	<input type="button" value="Add"/>
<input type="text" value="Hemochromatosis"/>	<input type="text" value="ABCD"/>	<input type="text" value="06/07/2011"/>	<input type="button" value="EDIT"/>
Other Medical Condition Hemochromatosis	Specify Type ABCD	Date Detected 06/07/2012	<input type="button" value="Add"/>

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 NO

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

Assay/Test Type:	Results:	Date:
<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>

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):

Assay/Test Type:

Results:

Date:

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:

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: - - ext. Mobile: - - ext. Pager/beeper: - - ext. Other: - - ext.

Email:*

Other contact info:

Submit

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!

Resolution 9

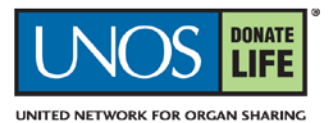
RESOLVED, that proposed enhancements to the Improving Patient Safety Portal for reporting potential donor-derived disease transmission events be programmed and implemented, effective pending programming and notice to the OPTN membership.

**Page 18 of Board book*

Questions?

Thank you.

OPTN



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?