West Nile Virus and Organ Transplantation: HRSA's Approach

Laura M. Saint Martin, M.D., M.P.H.

Medical Officer

Health Resources and Services Administration

Division of Transplantation

HRSA Role in Transplantation—Oversight

- Health Resources and Services Administration (HRSA), Special Programs Bureau, Division of Transplantation
  - OPTN [UNOS]
  - SRTR [URREA]
  - National Bone Marrow Donor Registry [NMDP]
  - Coordination of Organ and Tissue Donor Activities including Secretary's Initiative

Statutory Authority

- National Organ Transplant Act (NOTA) of 1984 (42 U.S.C. § 273, et seq.)
  - Created Organ Procurement and Transplantation Network (OPTN)
- Section 1138 of the Social Security Act (42 U.S.C § 1320b-8(a)(1)(B))

Initial Event

- August 2002
  - Four organ transplant recipients infected with WNV after receiving organs from same donor
  - Donor acquired WNV from blood transfused shortly before donation

HRSA/OPTN Response

- September 9, 2002
  - Alert Notice issued to OPTN
  - OPTN/UNOS Organ Procurement Organization Committee discussed issue; agreed that given the lack of an FDA-approved test for WNV, the best course of action is for OPOs to continue their thorough screening process for all types of infection (medical and social history, physical exam and medical testing)

HRSA/OPTN Response (cont.)

- September 20, 2002
  - Alert Notice issued to OPTN
  - possible WNV in recent liver recipient
  - Risk of transmitting WNV through organ transplant undetermined, but thought to be low
  - Advice of OPTN/UNOS OPO committee
  - Refer to CDC and FDA web sites

WNV Guidance to OPTN

- **Guidance for Use of West Nile Virus Diagnostic and Screening Tests in Organ Donation and Transplantation**
  - Issued by HRSA to OPTN on January 9, 2004
  - Approach developed with input from CDC, FDA, OPTN, transplant society reps, AOPO reps, transplant ID specialists

HRSA WNV Guidance

- Purpose
  - Inform OPTN about availability of investigational WNV screening test
  - Differentiate between uses of screening and diagnostic tests
  - Inform about practical limitations of screening with investigational tests
  - Recommend uses of screening tests
  - Recommend responses to screening test results

Practical Limitations of Screening Tests

- Specimens from organ donors accepted at limited number of testing sites
- Use of mini-pool vs. single sample testing
- Long test report turnaround time
- What to do with positive result after organ transplanted
- Heart must be beating when specimen obtained

HRSA Recommendations: General Measures

- Defer donors with encephalitis, meningitis, or flaccid paralysis of undetermined etiology in geographic areas with known human WNV activity
- If organ transplant recipient develops a febrile illness, perform a WNV IgM test and a WNV-NAT if WNV infection is clinically suspected.
- Consider screening of living donors with WNV-NAT as close to the time of donation as possible.

HRSA Recommendations: Deceased Donors

- If donor WNV-NAT reactive, and the organs have not been transplanted:
- Consider transplant only if potential recipient has an emergent, life-threatening illness when no other organs are available and no other lifesaving therapies exist.
- Inform the potential recipient of the risk and potential consequences of acquiring WNV infection.
- Consider enrolling the recipient in a clinical trial of Omr-IgG-am™ if the recipient develops symptoms suggestive of WNV infection and meets trial eligibility criteria.

HRSA Recommendations: Deceased Donors (cont.)

If donor WNV-NAT reactive, and organs already have been transplanted:

- Inform recipient of the risk and potential consequences of acquiring WNV infection
- Monitor recipient for development of symptoms; perform WNV IgM test and WNV-NAT if WNV is clinically suspected.
- Consider enrolling recipient in clinical trial of Omr-IgG-am™ if develops symptoms suggestive of WNV infection and meets trial eligibility criteria.

HRSA Recommendations: Living Donors

1 If donor WNV-NAT is reactive, and transplant is non-urgent:

- Defer the donor for 28 days

HRSA Recommendations: Living Donors (cont.)

1 If donor WNV-NAT is reactive, and potential recipient has an emergent, life-threatening illness when no other organs are available and no other lifesaving therapies exist:

- Inform recipient of risk and potential consequences of acquiring WNV infection
- Monitor recipient for symptoms; perform WNV IgM and WNV-NAT if WNV is clinically suspected
- Consider enrolling recipient in a clinical trial of Omr-IgG-am™ if develops symptoms suggestive of WNV infection and meets trial eligibility criteria

Contact Information

Laura M. Saint Martin, M.D., M.P.H.
(301) 443-7577
lstmartin@HRSA.gov

- DoT Website [www.hrsa.gov/osp/dot]
  - OPTN Final Rule
- OPTN Website [www.optn.org]
- SRTR Website [www.ustransplant.org]