INTERIM REPORT OF THE
OPTN/UNOS AD HOC DISEASE TRANSMISSION ADVISORY COMMITTEE

June 9, 2011

The OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee met via teleconference on Thursday, June 9, 2011, and considered the following items:

1. The Committee received a recap of the June 7-8, 2011, Advisory Committee of Blood Safety and Availability (ACBSA) meeting. The DTAC Chair and the liaison for the Operations and Safety Committee both presented during this meeting. Members of the ACBSA were eager to hear about the DTAC's role in tracking potential transmissions as well as the trends noted since data collection began in 2006. A recurring topic throughout the meeting was transplant tourism and the need to obtain more data in this area and resolve practical and ethical dilemmas related to this practice.

2. The Chair and a HRSA ex officio member briefly discussed Goal 6.2 (Reduce iatrogenic transmission of viral hepatitis associated with blood, organs and tissues.) in the US HHS Action Plan for the Prevention, Care and Treatment of Viral Hepatitis entitled "Combating the Silent Epidemic of Hepatitis." This goal outlined the need for:

    - (6.2.1) Promote development of rapid nucleic acid testing (NAT) testing and the potential development of new "pathogen reduction technology."
    - (6.2.2) Create a national cross-agency surveillance system to detect and assess the circumstances, risk behaviors and modes of transmission underlying transfusion and transplantation-related infections.
    - (6.2.3) Revise existing policy to implement NAT for HCV among organ donors

    The Committee discussed these goals in relation to the soon-to-be released US PHS Guidelines. While members understand the desire for NAT, there is still concern that there are still impediments to implementing requirements for NAT testing nationwide due to time constraints and concerns regarding false positive results.

3. The US PHS Guidelines are in the late stages of approval for public comment release in the Federal Register. The Chair anticipates a release for review and feedback in late June or early July at this point. A subcommittee has already been formed to review this proposed document and draft feedback for consideration by the full Committee.

4. The Uniform Donor Health Questionnaire (UDHQ) received a great number of comments while out for a brief period of review. A Focus Group with representation from a number of professional societies and the DTAC will be meeting in July to review comments received an updated draft of the UDHQ based upon this feedback. The Chair asked that members of the DTAC's subcommittee that reviewed the original draft in December 2010 review the new revised adult and child UDHQ forms and provide any feedback. A deadline was subsequently set for the end of June.

5. The Committee discussed concerns regarding several recent cases where additional screening beyond required donor testing was completed. The methods used for these tests were either research tests or off-label use of a testing kit that is not approved by the FDA for testing organ donors. The Committee plans to send a memo to the Membership and Professional Standards Committee (MPSC) regarding this study and its concerns related to the fact that IRB approval

may not be sought and there seems to be little protocol regarding potential recipient notification of this testing.

This issue will also be addressed by the AOPO's Organ Donation Research Consortium (ODRC), a multidisciplinary group interested in organ donor research. This group has subcommittees that are currently considering consent of organ donors for research purposes. This group hopes to give comment from an organ donation and OPO perspective on proposed research that involves organ donors.

The Committee will develop a newsletter regarding concerns related to research testing on donors once it receives MPSC feedback on this issue and hears more about the AOPO ODRC efforts.

6. The Chair encouraged members to consider submitting a late breaking abstract to the Interscience Conference on Anti-Microbial Agents and Chemotherapy (ICAAC), to be held on September 17-20, 2011. The deadline for any late breaking abstracts is August 1, 2011

7. The Committee reviewed eleven potential disease transmissions with 45 day follow-up and assigned tentative classifications to each. Three cases on the agenda were not covered due to time constraints, and will be discussed during the July 14, 2011, conference call.

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