Review of Minimum Screening Requirements for Deceased Donor Evaluation

Ad Hoc Disease Transmission Advisory Committee (DTAC) Committee

June 23-24, 2014

OPTN

UNOS DONATE LIFE

UNITED NETWORK FOR ORGAN SHARING

The Problem

- “Commercially available” is a vague policy requirement
- Current testing requirements do not reflect updates to testing technology
- Current policy is no longer in line with current testing practices in the field

Strategic Plan

- *Goal:* Promote transplant patient safety
- *Objective:* Increase capacity to identify patient safety issues

Goal of the Proposal

- Clarify and update policy language related to deceased donor screening
- Enhance patient safety
- Help OPOs better understand how to remain compliant with OPTN requirement for testing deceased donors by
  - Eliminating confusing policy language
  - Re-organizing policy to be more clear and concise
  - Bringing testing language in line with current laboratory practices

How the Proposal will Achieve its Goal

- Replace general screening test requirements with pathogen-specific requirements
- Remove the term “commercially available”
- Provide new option for HIV testing- combination Ag/Ab test
- Simplify syphilis testing requirement
- Add flexible language for Toxoplasma screening testing for heart donors

Public Comment Feedback

Public Comment Response Tally					
Type of Response	Response Total	In Favor	In Favor as Amended	Opposed	No Vote/ No Comment/ Did Not Consider
Individual	46	35 (76%)	0 (0%)	5 (11%)	6
Regional	11	10 (91%)	1 (9%)	0 (0%)	0
Committee	19	9 (47%)	0 (0%)	0 (0%)	10

Comment Themes

- Some concerns regarding offering diagnostic option for HIV
  - Will this encourage OPOs to replace NAT with Ag/Ab test due to cost?
  - Impact on contract labs?
- ASTS feedback on language suggested to replace “commercially available
  - Accepted ASTS feedback
  - Added requirement to report to Patient Safety System if HIV, HBV, or HCV testing not completed per policy

Estimates of window period length for different testing methods[1]

	Standard Serology	Enhanced Serology 4th generation or combination tests	NAT
HIV	**17-22 days**	**~7-16 days**	**5-6 days**
HCV	~70 days	~40-50 days	3-5 days
HBV	35-44 days	Not Applicable	20-22 days

1 Humar, A., Morris, M., Blumberg, E., Freeman, R., Preiksaitis, J., Kiberd, B., Schweitzer, E., Ganz, S., Caliendo, A., Orlowski, J. P., Wilson, B., Kotton, C., Michaels, M., Kleinman, S., Geier, S., Murphy, B., Green, M., Levi, M., Knoll, G., Segev, D., Brubaker, S., Hasz, R., Lebovitz, D. J., Mulligan, D., O'Connor, K., Pruett, T., Mozes, M., Lee, I., Delmonico, F. and Fischer, S. (2010), Nucleic Acid Testing (NAT) of Organ Donors: Is the 'Best' Test the Right Test? A Consensus Conference Report. *American Journal of Transplantation*, 10: 889–899. doi: 10.1111/j.1600-6143.2009.02992.x

Post-Public Comment Modifications

- Converted to plain language format
- Removed redundant language
- Replaces a “should” with a “must”
- Made PHS Guideline references consistent

2.811.C Required Information for Deceased Heart Donors

The host OPO must provide *all* the following additional information for all deceased donor heart offers:

1. Height
2. Weight
3. Vital signs, including blood pressure, heart rate, and temperature
4. History of treatment in hospital including vasopressors and hydration
5. Cardiopulmonary, social, and drug activity histories
6. Details of any documented cardiac arrest or hypotensive episodes
7. 12-lead interpreted electrocardiogram
8. Arterial blood gas results and ventilator settings
9. Cardiology consult or echocardiogram, if the hospital has the facilities
10. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B, Bw4, Bw6, C, DR, DR51, DR52, DR53, and DQB antigens
11. Toxoplasma antibody (Ab) test result or an appropriate donor sample sent with the heart for testing at the transplant hospital

Resolution 3 (page 8)

RESOLVED, that additions and modifications to Policies 2.3 (Evaluating and Screening Potential Deceased Donors), 2.4 (Deceased Donor Medical and Behavioral History), 2.5 (Hemodilution Assessment), 2.7 (HIV Screening of Potential Deceased Donors), 2.7.A (Exceptions to HIV Screening Requirement), 2.8 (Required Deceased Donor Information), 2.9 (Requested Deceased Donor Information) and its subsections, 2.10 (Post Recovery Follow Up and Reporting) and its subsections 16.4.D (Internal Labeling of Vessels, 2.11 (Deceased Donor Management), 2.12 (Organ Procurement) and its subsections, 2.13 (Requirements for Controlled Donation after Circulatory Death (DCD) Protocols) and its subsections, Table 14-2: Requirements for Living Kidney Donor Medical Evaluations, 14.5.A (Living Kidney Donor Psychosocial Evaluation Requirements), and 16.4.D (Internal Labeling of Vessels) as set forth in Resolution 3, are hereby approved, effective September 1, 2014.

Questions?

Thank you!

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Supporting Evidence

- HIV antigen/antibody combination testing recommended in 2013 PHS Guideline
  - not meant to replace NAT
  - Reduce the window period for recognizing infection
  - Feedback sought from the FDA
- Syphilis test options are equally effective and offer OPOs more flexibility
- Toxoplasma screening already requested regularly by heart transplant programs